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Supreme Court, U.S.
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No. 10-

IN THE

Supreme Court of the United States

HOWMEDICA OSTEONICS CORP.,

Petitioner,

v.

ZIMMER, INC. AND CENTERPULSE ORTHOPEDICS, INC. (FORMERLY KNOWN AS SULZER ORTHOPEDICS, INC.), AND SMITH & NEPHEW, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Has the U.S. Court of Appeals for the Federal Circuit improperly eroded or eliminated a patent-holder's Seventh Amendment right to a trial by jury in patent infringement cases by making the affirmative defense of invalidity for indefiniteness of patent claims (35 U.S.C. §112, ¶ 2) a pure question of law for the court?

2. Has the U.S. Court of Appeals for the Federal Circuit improperly treated invalidity of patent claims for indefiniteness as a pure question of law when the dispute arises around a factual determination of whether a value associated with patent claim language can be measured or calculated by persons of ordinary skill in the art using the disclosures of the patent?

RULE 14.1(B) AND 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), Petitioner Howmedica Osteonics Corp. ("Petitioner" or "Howmedica") states that all parties to the proceeding below appear in the caption of the case on the cover page.

Pursuant to Supreme Court Rule 29.6, Petitioner states that parent company—Stryker Corporation—owns 10 percent or more of the stock of Howmedica Osteonics Corp.

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Howmedica Osteonics Corp. ("Petitioner") hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion and order of the United States District Court for the District of New Jersey ("District Court") granting summary judgment in favor of Zimmer, Inc., Centerpulse Orthopedics, Inc. (formerly known as Sulzer Orthopedics, Inc.), and Smith & Nephew, Inc. (collectively "Respondents") is unreported and is set forth in the Appendix ("App.") at App. F & G. The opinion and order of the United States District Court for the District of New Jersey denying Petitioner's motion for reconsideration is unreported and is set forth at App. C & D. The order of the United States Court of Appeals for the Federal Circuit affirming (without opinion) the ruling of the District Court is unreported and is set forth at App. B. The order of the United States Court of Appeals for the Federal Circuit denying Petitioner's request for rehearing en banc is unreported and is set forth at App. A.

JURISDICTION

The District Court had jurisdiction to hear Petitioner's Complaint pursuant to 28 U.S.C. §§ 1331 and 1338. The Federal Circuit had jurisdiction to hear Petitioner's appeal pursuant to 28 U.S.C. §1295(a)(1). The Federal Circuit rendered its decision on October 13, 2010. Petitioner filed a timely petition for rehearing *en banc* by the Federal Circuit, which was denied on December 14, 2010. This Court's jurisdiction under 28 U.S.C. §1254(1) is thus timely invoked.

STATUTORY PROVISIONS INVOLVED

This case concerns whether patent invalidity for indefiniteness should be analyzed as a pure question of law or as a question of fact and/or question of law with underlying facts. 35 U.S.C. §112, paragraph 2 governs invalidity for indefiniteness, and provides in relevant part:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

STATEMENT OF THE CASE

This case raises important questions regarding a critical aspect of the law of invalidity of patents. The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") has held, subsequent to this Court's 1996 decision in *Markman v. Westview*, that patent invalidity for claim indefiniteness is analogous and/or similar to a court's responsibility to construe patent claims, and therefore should be treated, just like claim construction, as an issue solely for the court. *See Markman v. Westview Instruments*, 517 U.S. 370, 388 (U.S. 1996) (holding that claim construction is an issue for the court, as it involves interpretation of the terms of a legal instrument).

In particular, the Federal Circuit has held, since the 2001 *Exxon* decision, that invalidity for indefiniteness is a pure issue of law for the court, with no underlying questions of fact. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) ("a determination of claim indefiniteness is a legal conclusion

that is drawn from the court's performance of its duty as the construer of patent claims"). The Federal Circuit has created a test, which was followed by the District Court in this case, that "claims are considered indefinite when they are not amenable to construction or are insolubly ambiguous." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1351 (Fed. Cir. 2009).

However, as discussed herein, the Federal Circuit's treatment of indefiniteness as a pure issue of law is not supported by the Supreme Court's precedent, and is inconsistent with prior treatment of indefiniteness as a factual dispute. Moreover, the Federal Circuit's assumption that indefiniteness is akin to claim construction is incorrect, and does not apply to all indefiniteness issues—especially indefiniteness issues like the ones raised in this case.

Notably, the Supreme Court's *Markman* decision never addressed or considered the issue of invalidity for indefiniteness. *See Markman*, 517 U.S. 370. Indeed, none of the Supreme Court's reasons in *Markman* for finding claim construction to be a question of law is applicable in any way to invalidity for indefiniteness. *See id.*; *Tull* v. *United States*, 481 U.S. 412, 417 (1987) (whether an issue is for the court or jury "must depend on whether the jury must shoulder this responsibility as necessary to preserve the 'substance of the common-law right of trial by jury.'").

Moreover, in practical use, the Federal Circuit's rule does not always fit an indefiniteness dispute. Indefiniteness (a patent invalidity basis) is indeed quite different from claim construction and often involves more extensive factual issues than merely interpreting the meaning of a

claim term. Often, the dispute over a claim's definiteness is not whether the term can be construed or understood, but whether, as here, an easily understood patent claim term can be *calculated* or *measured* by a person of ordinary skill in the art. *See, e.g., Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1335 (Fed. Cir. 2003); *Marley Mouldings, Ltd. v. Mikron Indus.*, 417 F.3d 1356, 1358 (Fed. Cir. 2005); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1563 (Fed. Cir. 1996). In these situations, a court may face disputed factual determinations regarding whether such a skilled person can calculate or measure a claimed property or parameter—factual determinations that should be made by the jury.

This case involves such factual determinations on indefiniteness, and was improperly resolved as a pure question of law by the District Court. Here, each of the asserted claims of Petitioner's disputed patents relates to a polymer used in medical implants, and requires that it is heated for a time and temperature "***at least equivalent to heating . . . at 50°C for 144 hours as defined by the Arrhennius equation***." App. at 30a-31a. Notably, the legal construction of this claim language was never in dispute. App. at 90a-91a. In other words, the District Court and Respondents recognized that a person of ordinary skill in the art understands the ordinary *meaning* of the claim language. Rather, the indefiniteness dispute consisted entirely of whether a person of ordinary skill in the art possesses the knowledge to *calculate* or *measure* equivalent heating under the Arrhenius equation using the disclosures of the patent. App. at 41a-49a.

In moving for summary judgment of indefiniteness, Respondents bore the burden of proving patent invalidity by clear and convincing evidence. *See Ultimax Cement*

Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1351 (Fed. Cir. 2009) (a party asserting claim indefiniteness must satisfy "an evidentiary burden of clear and convincing evidence"). The Respondents, however, never provided any evidence that a person of ordinary skill could *not* calculate or measure the claimed equivalent heating. Indeed, Respondents did not provide any evidence or testimony at all from a person of ordinary skill in the art. App. at 41a, 12a. Rather, Respondents relied *only* on attorney argument regarding the definiteness of the claim term. App. at 12a. The District Court and Federal Circuit in turn accepted Respondents' attorneys' claim-construction-like arguments—over the unrebutted testimony of Petitioner's technical expert witnesses, who explained exactly how a person of ordinary skill in the art would, using the information in the patent specification, calculate and measure the claimed parameter. App. at 41a-49a, 11a-12a, 4a, 1a. Treating the issue as a pure question of law, the District Court declared that the patents provided insufficient instruction on how to calculate the Arrhenius equation claim terms. App. at 41a-49a. The court—not the jury—ruled on the factual evidence.

Petitioner respectfully submits, however, that if the indefiniteness issue had been treated as a question of fact, the lower courts could not have granted or affirmed summary judgment of indefiniteness. The lower courts would have recognized a genuine issue of material fact regarding the knowledge of a person of ordinary skill in the art, particularly in view of Petitioner's unrebutted expert testimony.

This issue has been the subject of recent scholarly discussion. *See, e.g.*, Comment, *The Federal Circuit: During Its Quarter-Century Existence, It Has Increasingly*

Positioned Itself as the Last Word in Patent Litigation, at the Expense of Uniformity, Predictability and Cost. Will the 'Super Juror' Learn from Its Mistakes?, 84 U. Det. Mercy L. Rev. 571, 594 (2007) (arguing that the Federal Circuit has adopted an "omnipotent role" of treating factual disputes as issues of law; "Following the reclassification of claim construction, the court reclassified indefiniteness as a legal conclusion, even though indefiniteness had previously involved underlying questions of fact that were reserved for the jury."); Comment, *Simplicity at the Cost of Clarity: Appellate Review of Claim Construction and the Failed Promise of Cybor*, 153 U. Pa. L. Rev. 763 (2004) (arguing that the reclassification of claim construction as an issue of law has "infected the issue of indefiniteness as well, in a way that has expanded the Federal Circuit's reviewing power while sending more mixed messages to district courts and potential litigants").

Moreover, this exact issue was also recently raised by another party before the *en banc* Federal Circuit. *See, e.g., Telecordia Tech. v. Cisco Sys., Inc.*, No. 2009-1175, -1184 (Fed. Cir. 2010) (Cisco, supported by amicus briefs filed by General Motors Corp. and Microsoft Corp., argued that indefiniteness should be a question of fact for the jury). The Federal Circuit declined to take up the issue.

Accordingly, this issue is of great importance to the Seventh Amendment right to a jury trial and the public's interest in upholding valid patents, and should be resolved by this Court.

The Technology at Issue

Petitioner's patents (U.S. Patent Nos. 6,174,934; 6,372,814; and 6,664,308) disclose a breakthrough

technology in the field of medical implants (such as artificial hip and knee replacement joints) made of ultra-high molecular weight polyethylene ("UHMWPE") materials. *See, e.g.*, Supplemental Appendix ("Supp. App.") at SA4-SA5. UHMWPE materials were first used in orthopedic applications in the 1960's. These prior UHMWPE implants, however, deteriorated over time as the UHMWPE oxidized and wore away. Supp. App. at SA4. Deteriorated implants resulted in pain for patients and often required additional surgeries. The UHMWPE materials and methods claimed in the patents-in-suit represent a major advance in this technology and provide beneficial advantages to patients by decreasing implant degradation. Supp. App. at SA4-SA5.

Specifically, the inventors of Petitioner's patents discovered that by, *inter alia*, irradiating and heating UHMWPE material at certain times and temperatures outside the presence of oxygen, UHMWPE degradation can be reduced. Supp. App. at SA 5. They discovered that heating "at least equivalent to heating . . . at 50°C for 144 hours as defined by the Arrhenius equation" resulted in an improved UHWMPE material. *Id.* A representative claim (claim 23 of the '934 patent) is set forth below:

> A medical implant comprising: an ultra-high molecular weight polyethylene material . . . said material irradiated . . . and then heated . . . *wherein the temperature and time are selected to be at least equivalent to heating said irradiated material at 50° C for 144 hours as defined by the Arrhennius' equation* (14).

Supp. App. at SA32, col. 13, lines 18-30 (emphasis added).

The central issue in this case, then, relates to whether and how a person of ordinary skill in the art would determine if a given time/temperature combination satisfies the claimed heating under the Arrhenius equation. The Arrhenius equation is described in each of the patents-in-suit as follows:

$$k_1 \text{ or } k_2 = A^*\exp(-\Delta H/([R]^*T)) \quad (14)$$

App. at 32a. In the Arrhenius equation, "k_1" and "k_2" are reaction rate constants, "A" is a reaction dependent constant, "ΔH" is the activation energy of reaction, "R" is the universal gas constant, and "T" is the absolute temperature (in degrees Kelvin) of the reaction. *Id.*

As explained by Petitioner's experts (and not disputed by Respondents), most of these values are either well known or cancel out when one is calculating equivalent time/temperatures using the Arrhenius equation. App. at 33a-34a. In other words, one of ordinary skill does not need to know the exact values of all of the Arrhenius equation constants and variables to determine equivalent heating. Meanwhile, there is no dispute that the sole necessary unknown variable, ΔH, can be calculated if two starting-point equivalent time/temperature combinations are known. App. at 41a-42a, 17a. Therefore, the ability to calculate or measure values under the claims boils down to one question—can a person of ordinary skill in the art identify two starting-point equivalent times/temperatures in the patent such that the Arrhenius equation can be applied to all time/temperature combinations to determine whether heating is equivalent?

Petitioner's experts say yes, and explained that the Arrhenius equation limitation can be calculated using two equivalent time/temperature combination disclosed in the common specifications of the disputed patents. App. at 42a-44a. Specifically, Petitioner's experts explained that the claims themselves disclose a first *minimum* time/temperature heating regimen of 50°C/144 hrs. App. at 43; Supp. App. at SA 32 ("wherein the temperature and time are selected to be *at least* equivalent to heating said irradiated material at 50° C for 144 hours as defined by the Arrhennius' equation") (emphasis added).) A second equivalent time/temperature regimen, therefore, is any other that is understood to be a *minimum* under the patents. The experts stated that they understood from the patent specification that at 130°C, the UHMWPE material must be heated for a minimum of 4 hours to obtain heating equivalent to that at 50°C for 144 hours. The experts stated that they understood 130°C/4 hours to be a second minimum heating in view of the following disclosure in the patents:

> For UHMWPE, this temperature range is between about 25°C and about 140°C. However, the preferred annealing temperature range is from about 37°C to about 135°C. The preferred time and temperature is 130°C for 20 hours with the **minimum** annealing time being about 4 hours (requiring a temperature at the high end of the range).

App. at 43a-45a, citing '934 patent at col. 5, lines 60-63 (emphasis added). Once these two minimum times/temperatures are used in the Arrhenius equation, the ΔH variable can be calculated through math that is simple

for persons of ordinary skill in the art. App. at 44a. Thereafter, infringement may be determined by applying the Arrhenius equation calculation to the heating time and temperature of an accused product or method. *Id.*

The District Court's Rulings

The District Court had jurisdiction to hear Petitioner's Complaint pursuant to 28 U.S.C. §§ 1331 and 1338.

On July 21, 2006, Respondents filed a motion for summary judgment of non-infringement and invalidity for indefiniteness of the '934, '814, and '318 patents. App. at 27a. Even though indefiniteness must be proven by clear and convincing evidence, Respondents relied entirely on attorney argument. Respondents failed to provide any expert testimony, or testimony from any other person of ordinary skill in the art, to rebut Petitioner's expert testimony regarding calculation of equivalent heating under the Arrhenius equation. Indeed, Respondents failed to provide any evidence at all that a person of ordinary skill in the art would be *unable* to use or calculate the Arrhenius equation to determine heating times and temperatures equivalent to 50°C for 144 hours. For example, Respondents never provided any expert declarations or testimony. App. at 41a, 12a.

The District Court nevertheless held that Respondents had met their clear and convincing burden on indefiniteness by identifying: (1) alleged insufficiencies in the testimony of Petitioner *Howmedica's* experts, (2) alleged "defects in *Howmedica's* evidence," and (3) Respondents' *attorney interpretation* of "citations to the patent specification and claim language." App. at 12a, 48a. The District Court

recognized that it must determine indefiniteness from the perspective of a "person of ordinary skill in the art." App. at 36a. The level of skill of such a person is exceedingly high—someone with a graduate degree and significant work experience. Nevertheless, the District Court ruled on its own over Petitioner's factual evidence and expert testimony, stating the following:

> Indefiniteness remains a matter of law, and the proper province of the court, ***even when the determination of claim's indefiniteness depends on an underlying issue of fact.*** In such circumstances the court will consider those underlying factual issues and rule on indefiniteness as a "matter of law on summary judgment."

App. at 35a-36a (emphasis added). In other words, even though disputed questions of material fact existed, the District Court decided them, rather than send those questions to the jury. On October 30, 2007, the District Court denied Petitioner's request for reconsideration. App. at 5a-21a.

The Federal Circuit's Rulings

On January 13, 2010, the District Court certified its summary judgment ruling for appeal pursuant to Federal Rule of Civil Procedure 54(b). Petitioner timely appealed to the Federal Circuit. The Federal Circuit had jurisdiction to hear Petitioner's appeal pursuant to 28 U.S.C. §1295(a)(1). On October 13, 2010, the Federal Circuit affirmed the District Court's ruling *per curium* (without opinion). App. at 3a-4a. Petitioner therefore petitioned for rehearing *en*

banc, reiterating that summary judgment was improper where Petitioner had offered disputed but unrebutted factual evidence and testimony. Petitioner asked the *en banc* Federal Circuit to reconsider its treatment of indefiniteness as a pure question of law. The Federal Circuit denied the petition for rehearing on December 14, 2010, again without opinion. App. at 1a-2a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's treatment of invalidity for indefiniteness as a pure question of law is not—as the Federal Circuit has justified it—based on this Court's legal precedent. Indeed, treating indefiniteness as a pure legal question is unsupported by this Court's precedent, and improperly deprives patent holders of their Seventh Amendment right to a jury trial. As discussed below, this Court's rationale for charging judges with the narrow responsibility of construing patent claim terms did not give the Federal Circuit *carte blanche* to extend that responsibility to other more dispositive and fact-intensive determinations, such as invalidity for indefiniteness.

Moreover, the Federal Circuit's rationale for treating indefiniteness as "akin" to claim construction is flawed. The Federal Circuit's test for indefiniteness ignores that (1) claim construction and indefiniteness have different standards and burdens of proof, (2) indefiniteness often, as in this case, may have little to do with the interpretation of a claim, but instead turns on extensive factual disputes regarding the measurement or calculation of a claimed parameter by a person of ordinary skill in the art, and (3) other more similar invalidity bases under §112 are treated as questions of fact or based on questions of fact.

As discussed in more detail below, this Court should grant certiorari to correct the Federal Circuit's misapprehension of this Court's precedent regarding claim construction, to curb the Federal Circuit's improper extension of that precedent to other more fact-intensive patent law inquires, and to ensure that patent holders receive their constitutionally guaranteed right to a jury trial.

I. THE FEDERAL CIRCUIT'S TREATMENT OF INDEFINITENESS IS NOT SUPPORTED BY THIS COURT'S PRECEDENT

A. The Supreme Court's *Markman* Decision Applied Only To Claim Construction, Not Indefiniteness

In 1996, this Court decided the historic *Markman* case, a key decision relating to patent law. *See Markman v. Westview Instruments*, 517 U.S. 370, 388 (U.S. 1996). In that decision, the Court considered the Seventh Amendment to the Constitution, which provides that "in Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved . . . ." U.S. Const., Amdt. 7. The Court explicitly recognized that patent infringement cases fall within that jury right. *See Markman*, 517 U.S. at 377 ("there is no dispute that infringement cases today must be tried to a jury, as their predecessors were more than two centuries ago"). *See also Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 603 (Fed. Cir. 1985) ("the right to a jury trial on issues of patent validity that may arise in a suit for patent infringement is protected by the Seventh Amendment"). The Court however, also recognized that some subsidiary

issues may be resolved by the judge without eroding this jury right. The Court stated that whether a specific issue will itself be a jury issue depends on whether "the guarantee [is] essential to preserve the right to a jury's resolution of the ultimate dispute." *Id.*

In *Markman*, the Court was faced with a dispute over who should have the responsibility for "construing" (i.e., interpreting) the claims of a patent. *Id.* There had long been a dispute over whether claim construction should be a task for the jury (as part of the jury's role in determining patent infringement or invalidity), or whether claim construction should be performed by the court (in a manner similar to construction of contracts). *See id.* In ruling that claim construction is a proper exercise for the judge, the Court recognized that claim construction is a subsidiary analysis that does not impugn the jury's resolution of the ultimate dispute. The Court found that "[t]he construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis." *Id.* at 388.

Importantly, the *Markman* decision only narrowly related to *construction* of patent claim terms—it never addressed whether any other substantive patent issues, such as invalidity, should be treated as a pure question of law for the judge. More particularly, the *Markman* decision made absolutely no mention of, and did not relate in any way to, invalidity for indefiniteness. *See Markman*, 517 U.S. 370.

B. The Federal Circuit Inconsistently Extended *Markman* To Indefiniteness

After *Markman*, the Federal Circuit still recognizes that most invalidity determinations, including other §112 disputes, are either entirely factual determinations or are based on underlying questions of fact. *See e.g., Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contrs. USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010) ("[e]nablement under § 112 is a question of law with underlying questions of fact"); *Yorkey v. Diab*, 601 F.3d 1279, 1283 (Fed. Cir. 2010) ("Whether the written description requirement [of §112] is met is a question of fact."); *Therma-Tru Corp. v. Peachtree Doors*, 44 F.3d 988, 993 (Fed. Cir. 1995) ("Whether the patentee does not satisfy the best mode provision of § 112 is a question of fact."). But the Federal Circuit now treats indefiniteness under §112 as a pure matter of law.

Indeed, prior to *Markman*, the lower courts typically treated indefiniteness under 35 U.S.C. §112 as involving underlying factual issues for the jury, and often gave the definiteness/indefiniteness question to the jury. *See, e.g., Beachcombers v. Wildewood Creative Prods.*, 31 F.3d 1154, 1158 (Fed. Cir. 1994) (reviewing denial of judgment as a matter of law after jury verdict of no indefiniteness; standard of review was whether substantial evidence supported the jury's fact findings on indefiniteness); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (reversing grant of JNOV after jury verdict of no indefiniteness; jury was entitled to rely on expert testimony of definiteness); *Konstant Prods. v. Frazier Indus. Co.*, 1993 U.S. Dist. LEXIS 7957 (N.D. Ill. June 7, 1993) ("While a determination of indefiniteness is

a question of law, it necessarily rests upon, like many legal questions, certain questions of fact.").

In 2001, however, the Federal Circuit revisited the issue of whether indefiniteness is an issue for the judge or the jury. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001). In *Exxon*, the Federal Circuit expressly rejected the argument that indefiniteness can involve underlying issues of fact that preclude summary judgment. *See id.* at 1376. The Federal Circuit based that ruling on the standard set forth by the Supreme Court in *Markman*, although again, *Markman* never considered indefiniteness. *See id.*, citing *Cybor Corp. v. Fas Techs.*, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (*en banc*) (discussing the Supreme Court's decision in *Markman* at length and reiterating its holding). The Federal Circuit held that because (1) indefiniteness (as the Federal Circuit assumed) always turns on whether claims can be construed, and (2) claim construction is a pure issue of law, then (3) indefiniteness must also be a pure issue of law. *See id.* The Federal Circuit proclaimed that "determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Id.*

As discussed in more detail *infra*, the Federal Circuit's initial assumption—that all indefiniteness issues turn on the ability to construe the claims—is erroneous. Indefiniteness is in fact a different legal principle from claim construction, with different analysis and factual considerations. But just as important, the Federal Circuit's reliance on *Markman* to treat indefiniteness as a pure issue of law is unwarranted.

C. The Supreme Court's Rationale In *Markman* Does Not Apply To Indefiniteness

In *Markman*, the Supreme Court articulated several different reasons for why a dispute, and claim construction in particular, may be treated as an issue for the court. *See Markman*, 517 U.S. at 377-390. None of those reasons exists in indefiniteness disputes.

First, invalidity for indefiniteness is not a subsidiary procedural issue. *See Markman*, 517 U.S. at 377-378 (the right to a jury trial must be guaranteed on issues that go to the "ultimate dispute"; one way of distinguishing such issues is by the "distinction between substance and procedure"). Here, claim indefiniteness is an invalidity basis that goes to the "ultimate dispute" of a patent case, and is often case dispositive. *See* 35 U.S.C. §112, ¶ 2 (indefiniteness is a basis for invalidating patent claims).

Second, patent claim indefiniteness does not appear to be an issue that was historically treated as a pure issue of law. *See Markman*, 517 U.S. at 377 (the question of whether to treat a question as legal or factual "may be easy because of clear historical evidence that the very subsidiary question was so regarded under the English practice"). Petitioner has found no historic common law decisions regarding indefiniteness of a patent. Indeed, the Court in *Markman* noted that at the time the Seventh Amendment was drafted, patent jury trials were themselves relatively new and primitive. *Id.* at 379. One of the few Supreme Court decisions addressing indefiniteness, however, (albeit under the pre-1952 patent statute) treated it as a question of fact. *See, e.g., United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 233 (U.S. 1942) (ruling patent was indefinite

based on factual evidence and testimony offered at trial), *appeal from* 37 F.Supp. 779, 780 (S.D. W.Va. 1941) (district court decision after trial "on the facts" included findings of fact on claim indefiniteness).

Third, indefiniteness is not an inquiry that is necessarily better suited for resolution by a judge than a jury. *See Markman*, 517 U.S. at 388 ("The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis."). Claim construction may be better suited for a judge because, like interpretation of a contract, it is an exercise into the *meaning* of terms in a written instrument to aid the ultimate resolution by the fact-finder. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008) ("'claim construction' is for the purpose of explaining and defining terms in the claims"); *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001) ("The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims."). Indefiniteness, however, asks whether a person of ordinary skill in the art can *apply* the patent claims, which often involves factual evidence and testimony relating to measuring or calculating a claimed property or parameter. *See, e.g., Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) ("A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not."). The jury is in a better position to weigh such factual evidence.

Fourth, indefiniteness does not present the same issues of uniformity as with claim construction. In *Markman*, the Court was concerned that different juries in different cases on the same patent might arrive at different claim constructions. *See Markman*, 517 U.S. at 390. For example, a patent claim could be construed one way to find infringement in a first case, but differently in a second case. *Id.* That concern, however, does not exist with respect to indefiniteness. If a patent claim is found to be invalid for indefiniteness in one case, that finding is preclusive. *See Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971) (a patentee cannot assert patents against a party which have been found to be invalid against another party). Conversely, while a finding of no indefiniteness is not preclusive against other parties, this is no different than with any other invalidity defense. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 n.3 (Fed. Cir. 1988) (discussing the non-preclusive effect of a judgment finding a patent not invalid). There is no more a concern with inconsistent jury findings of indefiniteness than there is with jury findings relating to other reasons for invalidity.

II. INVALIDITY FOR INDEFINITENESS IS NOT A PURE LEGAL ISSUE RELATED TO CLAIM CONSTRUCTION

The Federal Circuit's treatment of indefiniteness as an issue of law is also erroneous because indefiniteness should not be treated as simply part of claim construction analysis. *See Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009) ("Indefiniteness under 35 U.S.C. § 112 ¶ 2 is an issue of claim construction and a question of law that we review de novo."); *Exxon*, 265 F.3d at 1376.

Pursuant to statute, indefiniteness is a distinct legal theory of patent invalidity that must be proven by clear and convincing evidence. *See* 35 U.S.C. §§112, 282. Indefiniteness involves a different inquiry from claim construction and a different burden of proof. Indeed, in many situations (like the present case) indefiniteness has very little at all to do with claim construction. An indefiniteness inquiry more closely relates to the other invalidity bases under §112 (enablement, written description, and best mode), each of which are either questions of fact or involve underlying issues of fact. Moreover, at least in cases such as this one, indefiniteness turns on whether a parameter in readily understood claim language can *be measured or calculated* by a person of ordinary skill in the art, using the patent teachings. In such cases, there is no justifiable reason to treat indefiniteness as a matter of claim construction.

A. Claim Construction And Invalidity for Indefiniteness Involve Differing Standards and Burdens Of Proof

At their most fundamental level, claim construction and invalidity for indefiniteness are two different legal principles. The Federal Circuit has often implicitly recognized or hinted at the differences between these two legal principles, but has nevertheless improperly treated them as one-and-the-same.

Foremost, claim construction and indefiniteness involve different burdens of proof. Claim construction is a burden-less inquiry, in which both parties bear an equal task in advancing their definitions of the claim terms. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en*

banc) (articulating the rules for claim construction and describing no burden of proof); *Level One Communs. v. Seeq Tech.*, 987 F. Supp. 1191, 1196 (N.D. Cal. 1997) ("since claim construction is a question of law reviewed de novo, it makes no sense to apply burdens of proof"). In contrast, patents are presumed by statute to satisfy the definiteness requirement. *See* 35 U.S.C. §282, §112. A challenger must prove indefiniteness by clear and convincing evidence. *See Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1351 (Fed. Cir. 2009) (a party asserting claim indefiniteness must satisfy "an evidentiary burden of clear and convincing evidence"). Treating indefiniteness as a pure question of law makes it difficult, if not impossible, for a court to properly put a challenger to its burden of proof. In the present case, for example, the District Court determined that Respondents met their burden, not by presenting their own clear and convincing evidence that a person of ordinary skill could *not* measure or calculate the disputed claim limitation, but rather by finding alleged insufficiencies and defects in Petitioner's evidence. App. at 12a, 48a.

Moreover, claim construction and indefiniteness involve fundamentally different inquiries. Again, claim construction involves determining "what the words in the claim *mean*." *See Markman*, 517 U.S. at 374 (emphasis added); *Abbott*, 544 F.3d at 1360 ("'claim construction' is for the purpose of explaining and defining terms in the claims . . . ."). An indefiniteness inquiry, however, asks whether a person of ordinary skill in the art can determine *what falls within those claims*. *See Geneva*, 349 F.3d at 1384 ("A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not.") As

the Federal Circuit itself has recognized, "[e]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim *scope*." *Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008) (emphasis added).

The differences between claim construction and indefiniteness can be easily seen in this case. Here, the patent language "*at least equivalent to heating . . . at 50°C for 144 hours as defined by the Arrhennius equation*" was never disputed for purposes of claim construction. App. at 90a-91a. There was no dispute that the Arrhenius equation, and equivalent heating under the Arrhenius equation, are well understood concepts to persons skilled in this technical field. *Id.* Indeed, in the District Court's April 23, 2007 claim construction Order, the District Court found (as the parties had agreed) that the Arrhenius equation term had a clear ordinary meaning that did not need further construction. App. at 90a-91a. Pursuant to the Federal Circuit's law that claims are only indefinite if they are "not amenable to construction," the District Court's claim construction should have eliminated any indefiniteness challenge. *See Ultimax*, 587 F.3d at 1352. The District Court, however, later found the claims indefinite on the basis that "a person of ordinary skill in the art would not be able to discern *whether a competitor's similar product actually infringes on Howmedica's patents*." App. at 49a (emphasis added). That inquiry has much more to do with determining infringement, which is a question of fact, than it does claim construction. *See Markman*, 517 U.S. 370 ("whether infringement occurred [] is a question of fact for the jury"). It can hardly be said that this Court finding was done as part of the "court's

performance of its duty as the construer of patent claims." *Exxon*, 265 F.3d at 1376.

B. Indefiniteness Based On Alleged Inability To Calculate Or Measure A Parameter Is Not Related To Claim Construction

The facts of this case—where indefiniteness turned *not* on the ability to define claim language, but rather on the ability of a person of ordinary skill in the art to measure or calculate the claim term—are not unique. Indeed, the Federal Circuit has repeatedly considered such cases, none of which can easily be shoe-horned into a pure "legal issue" claim construction analysis.

The Federal Circuit has found claims to be indefinite as a pure question of law, even though the dispute failed to fit neatly into a claim construction analysis. For example, in *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1335 (Fed. Cir. 2003), the claims required a "melting point elevation of between 2 degrees to 10 degrees." The term itself was easy to understand. However, *measuring* that melting point elevation proved more difficult, as it differed based on the four possible sample preparation methods available. *Id.* at 1336-1337. The Federal Circuit found, based on extrinsic factual evidence regarding these four possible methods, that the claims were therefore indefinite. The Federal Circuit, however, treated the issue as a pure question of law.

Conversely, the Federal Circuit has also found claims to be definite as a matter of law, even though the dispute did not relate to claim construction. For example, in *Marley Mouldings*, the claim term in dispute was "parts (volume)"

of "wood flour." *Marley Mouldings, Ltd. v. Mikron Indus.*, 417 F.3d 1356, 1358 (Fed. Cir. 2005). The indefiniteness dispute was not over the construction of "parts (volume)" or "wood flour." *Id.* Rather, the District Court found indefiniteness because "the means to calculate the percent volume of wood flour" was not specified in the patent. *Id.* Because factual evidence showed that the parameter could be "calculated or measured" by a person of ordinary skill, however, the Federal Circuit reversed. *See id.* at 1361-62.

Similarly, in *PPG Indus.*, a defendant asserted that claims requiring "ultraviolet transmittance" within a certain range were indefinite. *See PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1563 (Fed. Cir. 1996). The defendant did not dispute the meaning of the term "ultraviolet transmittance" itself, however. *See id.* Rather, the defendant asserted that the term was indefinite because the patent did not specify how to measure the claimed property. *See id.* The Federal Circuit affirmed a finding of definiteness based on factual evidence that a person of ordinary skill in the art would know that each of the four known measurement methods produced the same result. *See id.*

None of these cases involved a pure legal interpretation of the patent claims. Rather, each of these cases involved a weighing of factual evidence regarding the ability to calculate or measure a disputed claim term. In these types of cases, it makes no sense to treat indefiniteness as a pure question of law, but the Federal Circuit refuses to deviate from its post-*Markman* rule for indefiniteness.

This case is an extension of the unworkable claim-construction-like indefiniteness test propagated by those

Federal Circuit decisions. Here, genuine issues of material fact exist regarding *not* whether claim language can be understood or defined, but whether the parameters of that claim language for determining infringement can be *measured* or *calculated*. Petitioner's expert witnesses explained how a person of ordinary skill in the art would measure equivalent heating through mathematical calculations. App. at 42a-44a. Those experts stated that one of ordinary skill in the art would do so using two starting-point equivalent minimum time/temperature combinations from the patent specifications (50°C/144 hrs and 130°C/4 hrs). (*Id.*) The lower court's rulings in this case resolved this factual dispute against Petitioner—without any contrary expert testimony from Respondents.

The Federal Circuit's erroneous test appears to have originated in those indefiniteness cases that do tend to present themselves during claim construction. Some indefiniteness cases involve subjective terms or words of degree in a claim. For example, in *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1312 (Fed. Cir. 1998), the claims required concrete that was "hardened sufficiently." It is easy to see why the court would treat the issue of whether the claim was definite (i.e., whether a person of ordinary skill in the art can determine what is "sufficiently" hardened under the claim) as an issue of claim construction (i.e., the meaning of the term "hardened sufficiently"). That is because the dispute involved the meaning of the claim language itself, unlike here. Even in that case, though, the definiteness issue did not strictly revolve around defining the term. Rather, the Federal Circuit found the claims to be definite because of sufficient qualitative and quantitative tests in the specification to determine the requisite hardness. *Id.*

at 1312. But in any event, simply because indefiniteness issues do, in some cases, arise during claim construction does not warrant that they should all be subsumed by that analysis.

C. Indefiniteness Is More Closely Related To Other Invalidity Bases Involving Questions of Fact

Finally, the Federal Circuit's treatment of indefiniteness as a pure issue of law is inconsistent with its treatment of other invalidity bases under §112, which involve much closer analyses to indefiniteness than does claim construction. Namely, apart from indefiniteness, §112 has been interpreted to include three other requirements for patentability: "enablement," "written description," and "best mode." Each of these patentability requirements is treated as either a question of fact for the jury, or based on one or more underlying questions of fact.

For example, the enablement requirement arises from the language in §112 that the specification must contain sufficient disclosure so "as to enable any person skilled in the art to which it pertains . . . to make and use [the invention]." 35 U.S.C. §112, ¶ 1. The relevant inquiry is whether the claims are enabled based on "the objective knowledge of one of ordinary skill in the art." *Singh v. Brake*, 317 F.3d 1334, 1345 (Fed. Cir. 2002). Enablement is a "question of law with underlying questions of fact" and "factual issues" arising from expert testimony can preclude summary judgment. *See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contrs. USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010). Just like enablement, indefiniteness also inquires into

the knowledge of one of ordinary skill in the art. *See Fisher-Price, Inc. v. Graco Children's Prods.*, 154 Fed. Appx. 903, 905 (Fed. Cir. 2005) ("A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not."). But indefiniteness is inexplicably treated as a pure question of law, whereas enablement is not.

Section 112 also requires a "written description of the invention." 35 U.S.C. §112, ¶ 1. The relevant inquiry is whether the patent has described "an invention understandable to a person of ordinary skill in the art and show[s] that the inventor actually invented the invention claimed." *Centocor Ortho Biotech v. Abbott Labs.*, 2011 U.S. App. LEXIS 3514 (Fed. Cir. 2011). In other words, the written description requirement under §112 also involves the understanding of persons of ordinary skill in the art as to the relationship between the claims and the specification. However, "[c]ompliance with the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact." *Id.*

Lastly, §112 contains a "best mode" requirement. 35 U.S.C. §112, ¶ 1 (the specification "shall set forth the best mode contemplated by the inventor of carrying out the invention"). Just like the other requirements of §112, the best mode requirement compares the claims to what is disclosed in the specification. Best mode resolution includes an analysis of "whether the inventor has disclosed the best mode and whether the disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention." *Green Edge Enters., LLC v. Rubber Mulch, LLC*, 620 F.3d 1287, 1296 (Fed. Cir. 2010).

Whether the best mode requirement is met is "a question of fact." *Id.*

Notably, the enablement, written description, and best mode requirements under §112, as well as the definiteness requirement, *all* involve an analysis of the claims in view of the patent specification. *See supra*; *see also Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 1371 (Fed. Cir. 2009) ("If a claim fails to reasonably apprise one skilled in the art of the boundaries of the claim when read in light of the specification, then the claim is invalid under § 112 for indefiniteness."); *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983) (finding claims not indefinite when the specification provided "a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine whether" the claim limitation was satisfied). Each of these §112 analyses is based on the understanding of persons of ordinary skill in the art regarding the patent claims and specification. *See supra*, citing cases. Accordingly, the Federal Circuit's treatment of only one §112 requirement—indefiniteness—as a pure matter of law finds no justification in the statute and makes no sense. As such, the Federal Circuit's post-*Markman* treatment of indefiniteness unilaterally and improperly denies patent holders the right to a jury trial on genuinely disputed issues of material fact.

CONCLUSION

The time has come to address these issues squarely. To give proper direction to the Federal Circuit and to the public on important patent rights and the proper framework for determining patent invalidity for indefiniteness, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — ORDER DENYING PETITION FOR REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED AND FILED DECEMBER 14, 2010

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A petition for rehearing en banc having been filed by the Appellant, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 21, 2010.

FOR THE COURT,
s/
Jan Horbaly
Clerk

Appendix A

Dated: 12/14/2010

cc: Gregory J. Vogler
David Callahan, Gregory Stillman

HOWMEDICA OSTEONICS V ZIMMER INC, 2010-1162 (DCT -05-CV-0897)

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT
DEC 14 2010
JAN HORBALY
CLERK

APPENDIX B — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED OCTOBER 13, 2010

NOTE: This disposition is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2010-1162

HOWMEDICA OSTEONICS CORP.,

Plaintiff-Appellant,

v.

ZIMMER, INC. and
CENTERPULSE ORTHOPEDICS, INC.
(formerly known as Sulzer Orthopedics, Inc.),

Defendants-Appellees,

and

SMITH & NEPHEW, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of New Jersey in No. 05-CV-0897, Senior Judge William H. Walls.

Appendix B

JUDGMENT

GREGORY J. VOGLER, McAndrews, Held & Malloy, Ltd., of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were TIMOTHY J. MALLOY, PATRICIA J. MCGRATH and CHRISTOPHER M. SCHARFF.

DAVID K. CALLAHAN, Kirkland & Ellis LLP, of Chicago, Illinois, argued for all defendants-appellees. With him on the brief for Zimmer, Inc., et al. was BRYAN S. HALE. Of counsel was BRYCE A. MAUTNER. Also on the brief for Smith & Nephew, Inc., were GREGORY N. STILLMAN, Hunton & Williams LLP, of Norfolk, Virginia; RODGER L. TATE and BRADLEY T. LENNIE, of Washington, DC.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (BRYSON, DYK, and MOORE, *Circuit Judges*).

AFFIRMED. ***See*** **Fed. Cir. R. 36.**

ENTERED BY ORDER OF THE COURT

October 13, 2010
Date

/s/
Jan Horbaly
Clerk

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT, DISTRICT OF NEW JERSEY, DATED OCTOBER 30, 2007

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. No 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.,

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

OPINION

Walls, Senior District Judge

Presently before the Court is a motion by plaintiff Howmedica Osteonics Corp. ("Howmedica") seeking reconsideration of the Court's June 13, 2007 Order granting defendants Zimmer, Inc.'s, Zimmer Austin, Inc.'s, and Smith & Nephew, Inc.'s joint motion for summary judgment. Having considered the parties' written submissions, the Court denies Howmedica's motion for reconsideration.

Appendix C

NOT FOR PUBLICATION

I. FACTS AND PROCEDURAL HISTORY[1]

In February 2005, Howmedica brought this action against Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. (collectively the "defendants"), alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants. These four patents are U.S. Patent No. 6,174,934 B1 (filed Jan. 23, 1998) ("the '934 patent"); U.S. Patent No. 6,372,814 B1 (filed June 28, 2000) ("the '814 patent"); U.S. Patent No. 6,664,308 B2 (filed Jan. 8, 2002) ("the '308 patent"); U.S. Patent No. 6,818,020 B2 (filed June 13, 2003) ("the '020 patent") (collectively, "the patents-in-suit"). Howmedica claims that four of the defendants' products, Longevity, Prolong, Durusul, and XLPE, infringe on these patents. The '020 patent is a continuation of application No. 10/041,118, now the '308 patent, which is a continuation of application No. 09/604,868, now the '814 patent, which is a continuation of application No. 09/012,345, now the '934 patent. All four patents share the same specification.

On July 21, 2006, defendants filed a joint motion for summary judgment on the issues of noninfringement

1. The factual background is recounted in the Court's June 13, 2007 Opinion whereby the Court granted defendants' motion for summary judgment. This opinion will include only facts pertinent to the disposition of the motion presently before the Court.

Appendix C

NOT FOR PUBLICATION

and invalidity of the asserted claims in the '934, '814, and '308 patents. Defendants argued that they are entitled to summary judgment on invalidity because the patent claims have a common claim term, the Arrhennius equation, that is not amenable to construction by a person of ordinary skill in the art. Alternatively, defendants claimed that they are entitled to summary judgment on noninfringement because Howmedica was unable to demonstrate how defendants' products infringe on these three patents.

On April 23, 2007, the Court issued its *Markman* Order construing the claim terms and phrases needing construction as identified by the parties. The parties argued the motion for summary judgment on May 15, 2007. The Court found that the Arrhennius equation term in the '934, '814, and '308 patents is insolubly ambiguous. On June 13, 2007, the Court issued its Opinion and Order granting defendants' motion for summary judgment on the issue of invalidity. The Court did not consider defendants' motion for summary judgment on noninfringement because this issue became moot.

Howmedica moves for reconsideration of the Court's June 13, 2007 Order pursuant to Local Civil Rule 7.1(i) on the grounds that this Court overlooked dispositive factual and legal issues which would have favored a ruling for Howmedica.

Appendix C

NOT FOR PUBLICATION

II. LEGAL STANDARD

A motion for reconsideration is governed by L. Civ. R. 7.1(i). The decision of whether to grant a motion for reconsideration is within the discretion of the district court. *See Le v. Univ. of Pa.*, 321 F.3d 403, 405-06 (3d Cir. 2003). A motion for reconsideration should be granted only when the movant shows either "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Café v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). Because reconsideration of a judgment after its entry is an extraordinary remedy, requests pursuant to these rules should be granted "sparingly," and only when "dispositive factual matters or controlling decisions of law" are brought to the court's attention but not considered. *Yurecko v. Port Auth. Trans-Hudson Corp.*, 279 F. Supp. 2d 606, 609 (D.N.J. 2003).

L. Civ. R. 7.1(i) requires the party moving for reconsideration to file a "brief setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked." L. Civ. R. 7.1(I). The movant must focus its arguments on what the court may have overlooked because the purpose of this limitation is to "encourage parties to present their positions as completely as

possible, and to prevent parties from filing a second motion, with the hindsight provided by the court's analysis, covering issues that should have been raised in the first set of motions." *United States v. Jones*, 158 F.R.D. 309, 314 (D.N.J. 1994). The movant may not use a motion for reconsideration to "relitigate old matters, nor to raise arguments or present evidence that could have been raised prior to the entry of judgment." *P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 352 (D.N.J. 2001)(citing Charles A. Wright et al., *Federal Practice and Procedure* § 2810.1 (2d ed. 2006)).

III. DISCUSSION

Howmedica does not argue that either an intervening change in the controlling law or new evidence not available when the Court decided the motion for summary judgment requires the Court to reconsider its June 13, 2007 Order. *Max's Seafood Café*, 176 F.3d at 677. Rather Howmedica presents four arguments that the Court overlooked dispositive factual and legal issues which resulted in a clear error of law or fact. Howmedica argues that the Court (1) misplaced the burden of proof on Howmedica to establish claim definiteness; (2) overlooked facts in the record or readily ascertainable from the patent specification that would establish claim definiteness; (3) overlooked the law on claim differentiation; and (4) blurred the legal standards between claim construction, claim definiteness and infringement.

Appendix C

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A. Burden of Proof on Claim Definiteness

Howmedica argues that the Court misplaced the burden of proving claim definiteness on Howmedica. As the Court noted in its June 13, 2007 Order, any patent approved by the United States Patent & Trademark Office ("PTO") has a "statutory presumption of validity." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). The burden of proving a patent's invalidity rests with the party that challenges its validity. 35 U.S.C. § 282. To meet that burden, the party challenging validity bears the burden of proving, by clear and convincing evidence, that the invention fails to meet the requirements of patentability. *Hewlett-Packard Co. v. Bausch & Lomb*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). (Dkt. 176, June 13, 2007 Opinion, at 10.)

Howmedica's assertion that the "burden of proof never shifts to the patentee to prove validity" is correct but incomplete. (Dkt. 181-5, Howmedica's Br., at 2)(citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 200). In *Pfizer*, the Federal Circuit explained the different burdens between the patentee and the party changing the patent's validity. *Id.* at 1359-60. "[O]nce a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence." *Id.* at 1360. Howmedica need not submit evidence to support the conclusion that its patent remains valid, but "once a challenger introduces evidence that might lead to a conclusion of invalidity-

what we call a prima facie case-the patentee 'would be well advised to introduce evidence sufficient to rebut that of the challenger.'" *Id.* (quoting *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986)). The district court's responsibility is to determine whether the challenging party "has met its burden by clear and convincing evidence by considering the totality of the evidence, including any rebuttal evidence presented by the patentee." *Id.*

The Court noted in its June 13, 2007 Opinion that whether a particular patent is "invalid for indefiniteness presents a question of law," *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001), because "claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Comm'ns, L.L.C. v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). Indefiniteness remains a matter of law, and the proper province of the court, even when the determination of claim's indefiniteness depends on an underlying issue of fact. *Exxon*, 365 F.3d at 1376. In such circumstances the court will consider those underlying factual issues and rule on indefiniteness as a "matter of law on summary judgment." *Id.* (Dkt. 176, June 13, 2007 Opinion, at 8.) In order for the court to construe the claim term, it must consider both the challenging party's prima facie case of invalidity and the patentee's rebuttal evidence.

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The Court recognized the presumption of the '934, '814, and '308 patents' validity but found that "[d]efendants have proven by clear and convincing evidence that the Arrhennius' equation terms" in these three patents "are insolubly ambiguous." (Dkt. 176, June 13, 2007 Opinion, at 18.) The Court disagrees with Howmedica's protest that defendants used only attorney arguments to support their prima facie case of claim indefiniteness. Defendants provided testimony from Howmedica's expert witnesses, defects in Howmedica's evidence and, most importantly, citations to the patent specification and claim language. (Dkt. 176, June 13, 2007 Opinion, at 17-18.) As the Federal Circuit has repeated often, the meaning of a claim is determined by using intrinsic evidence, which includes the claims, the specification, and the prosecution history and, if necessary, by using extrinsic evidence, which includes expert and inventor testimony, dictionaries and learned treatise. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-19 (Fed. Cir. 2005)(en banc). Howmedica's use of expert testimony "is less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). The Court considered the claim language and the patent specification as the primary sources for construing the Arrhennius equation term.

Howmedica protests that defendants raised for the first time in their reply that the indefiniteness of the "Arrhennius equation" stemmed from the inability to

determine a second post-irradiation heating time/temperature combination disclosed in the patents-in-suit. The Court gave Howmedica an opportunity to respond to defendants' new argument in its surreply. (Dkt. 112, Howmedica's surreply, at 1.) The Court also gave Howmedica ample opportunity to address defendants' new argument during the May 15, 2007 Summary Judgment Hearing. (May 15, 2007 Tr., at 33.) The Court, after considering the totality of the evidence, found that "the specification discloses at least three time/temperature pairs that *could* be equivalent to 144 hours and 50°C." (Dkt. 176, June 13, 2007 Opinion, at 18.) For this reason, the Court found the Arrhennius equation term "insolubly ambiguous." The Court did not overlook the law on the burden of proving invalidity nor denied Howmedica the opportunity to respond to defendants' new prima facie case that the Arrhennius equation term was indefinite.

B. Overlooked Facts in the Record or in the Patent Specification

Howmedica argues that the Court "may have overlooked explanations for the issues first raised in Defendants' Reply brief and relied upon by the Court." (Dkt. 181-5, Howmedica's Br., at 5.) Howmedica reargues two of the Court's findings: (1) that "[n]either counsel nor Howmedica's experts can provide any reason for their belief that a person of ordinary skill in the art would pair 4 hours with 130°[C], rather than 135°C or 140°C" and (2) that Howmedica and its experts

do not explain the purported ambiguity between the fact that "144 hours (at 50°C) is a preferable heating time, but 4 hours (at 130°C, 135°C, or 140°C) is a minimum time." ((Dkt. 181-5, Howmedica's Br., at 5 (quoting Dkt. 176, June 13, 2007 Opinion, at 17, 18)). Both findings relate to Howmedica's position that heating at 130°C for 4 hours is equivalent to heating at 50°C for 144 hours.

Howmedica dissects the partial phrase, "[t]he preferred time and temperature is 130°C at 20 hours with the minimum annealing time being about 4 hours," from the patent specification to support its argument that heating at 130°C for 4 hours is equivalent to heating at 50°C for 144 hours. ((Dkt. 181-5, Howmedica's Br., at 5 (quoting '934 patent, col. 5, lns. 60-62).) Howmedica argues that a person of ordinary skill in the art would pair a heating temperature of 130°C with a minimum heating time of 4 hours. (Dkt. 181-5, Howmedica's Br., at 5.) Ironically, Howmedica overlooked the context of its quote.[2] The Court found that there is no support in

2. The patent specification provides in relevant part:

> For UHMWPE, this temperature range is between about 25° C and about 140° C. However, the preferred annealing temperature range is from about 37° C to about 135° C. The preferred time and temperature is 130° C for 20 hours with the minimum annealing time being about 4 hours (***requiring a temperature at the high end of the range***).

('934 patent, col. 5, lns. 57-63) (emphasis added).

the specification that 130°C is "described as at 'the high end of the range'" and thus should be paired with a heating time of 4 hours. (Dkt. 176, June 13, 2007 Opinion, at 16.)

Despite the fact that the Court explained the reasons for its findings, Howmedica rehashes the same arguments. Howmedica's disagreement with the Court's reasoning is not a proper basis for the grant of reconsideration. *Oritani Sav. & Loan Ass'n v. Fidelity & Deposit Co. of Maryland*, 744 F. Supp. 1311, 1314 (D.N.J. 1990) ("A motion for reconsideration is improper when it is used 'to ask the Court to rethink what is had already thought through-rightly or wrongly.'").

C. Law on Claim Differentiation

Howmedica argues that the Court overlooked the law on claim differentiation by taking an overly-broad analysis of the claims and by assuming that "each of the asserted claims required that the heating performed consistent with the Arrhennius equation to 'achieve the same level of crosslinking.'" (Dkt. 181-5, Howmedica's Br., at 7.) Despite the fact that the Court cannot find where Howmedica has raised this argument in Howmedica's *Markman* briefs, the *Markman* hearing, Howmedica's opposition and surreply briefs on the motion for summary judgment, and the summary judgment hearing. Nor does Howmedica point to where and when this argument was presented and then

overlooked by the Court. The Court finds this argument to be a red-herring and improper. *United States v. Jones*, 158 F.R.D. 309, 314 (D.N.J. 1994) (explaining that a motion for reconsideration is limited "to prevent parties from filing a second motion, with the hindsight provided by the court's analysis, covering issues that should have been raised in the first set of motions.").

Rather than dismiss Howmedica's argument because Howmedica failed to raise this argument earlier, the Court will examine the merits of this argument. Howmedica's argument does not address the dispositive issue. Howmedica argues, for example, that claim 23 of the '934 patent "requires that the heating times and temperatures are 'equivalent,' ***not that the level of cross-links must be the same or equivalent.***" (Dkt. 181-5, Howmedica's Br., at 8 (emphasis added).) The Court decided that all the claims are indefinite because the Arrhennius equation term is indefinite and not because each claim required the same level of cross-linking.

Every independent claim at issue contains the Arrhennius equation term. Claim 23 of the '934 patent is representative of these claims:

> A medical implant comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated to create free radicals in the absence of a free radical generation catalyst while out of contact with oxygen . . .

> and then **heated** while out of contact with oxygen . . . **at a temperature of greater than 25°C for a sufficient time to create a level of cross-links between free radicals wherein the temperature and time are selected to be at least equivalent to heating said irradiated material at 50°C for 144 hours as defined by the Arrhennius' equation (14).**

'934 Patent, claim 23 (emphasis added).[3] The Arrhennius equation term is indefinite is because a person of ordinary skill in the art cannot derive the various unknown terms in the Arrhennius equation. A person of ordinary skill in the art cannot derive these unknown terms because the specification does not disclose a temperature/time pair that could be equivalent to the 50°C for 144 hours as defined by the Arrhennius equation. (Dkt. 176, June 13, 2007 Opinion, at 17-18.)

Whether the level of cross-linking should vary among the different claims would not change the Court's opinion about the Arrhennius equation term. The Court

3. The following claims are at issue in this motion for summary judgment: claims 23, 27, 29, 50, and 52 of the '934 Patent; claims 7, 12, and 19 of the '814 Patent; and claims 1, 5, 10, 12, 16, 21, 23, and 24 of the '308 Patent. All of these claims either incorporate the Arrhennius' equation term, or are dependent from claims that incorporate that term.

found that this term, which was a common claim limitation in all claims at issue, was insolubly ambiguous.

D. Law on Claim Construction, Claim Definiteness and Infringement

Howmedica argues that the Court overlooked its role by blurring the separate legal standards between claim construction, claim definiteness and infringement. First, Howmedica argues that the Court ignored canons of claim interpretation by incorrectly finding that alternative interpretations is tantamount to claim indefiniteness. The Court notes that Howmedica mis-characterizes the Court's opinion by this argument. Howmedica, identifying four possibilities, wrote: "The only deficiency the Court perceived was which of the following time/temperature pairs to select: 20 hours at 130°C, 4 hours at 140°C, 4 hours at 135°C, or ***4 hours at 130°C***." (Dkt. 181-5, Howmedica's Br., at 10 (emphasis added).) However, the Court rejected the time/temperature pair of 4 hours at 130°C as a possibility and considered at least three other pairs as possible. "Contrary to Howmedica's assertions, the specification discloses at least three time/temperature pairs that *could* be equivalent to 144 hours at 150°C, the first being the most plausible: (1) 20 hours at 130°C, (2) 4 hours at 140°C, and (3) 4 hours at 135°C." (Dkt. 176, June 13, 2007 Opinion, at 18.)

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The Court rejected the time/temperature pair of 4 hours at 130°C, despite Howmedica's repeated arguments and expert testimony, because the patent specification does not support Howmedica's position. (Dkt. 176, June 13, 2007 Opinion, at 17.) The Court could not find that there were reasonable, alternative claim constructions to save the patent claims. Rather the Court found the Arrhennius equation term insolubly ambiguous because "the specification discloses at least three time/temperature pairs that *could* be equivalent to 144 hours at 150°C." (Dkt. 176, June 13, 2007 Opinion, at 17-18.)

Howmedica argues that the Court overlooked the distinction between claim definiteness and infringement. (Dkt. 181-5, Howmedica's Br., at 10.) Howmedica argues that the Court applied the wrong standard when the Court held that "[b]ecause a person of ordinary skill in the art would not be able to discern whether a competitor's similar product actually infringes on Howmedica's patents, the Court finds the claims indefinite." (Dkt. 181-5, Howmedica's Br., at 10 (quoting (Dkt. 176, June 13, 2007 Opinion, at 11, 18).) Howmedica advances *SmithKline Beecham Corp. v. Apotex Corp.*, for the proposition that "the test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim

delineates to a skilled artisan the bounds of the invention." 403 F.3d 1331, 1340-41 (Fed. Cir. 2005).[4]

First, the quoted language of the Court's June 13, 2007 Opinion must be placed in context where the Court explained in the previous sentence that "[i]f a person of ordinary skill in the art assumes that any one of these three alternatives is equivalent to 144 hours at 50°C, she will arrive at an entirely different interpretation of the scope of Howmedica's patents from that proposed by Howmedica's expert." (Dkt. 176, June 13, 2007 Opinion, at 18.) The key here is that the scope of the patent is unclear to a person of ordinary skill in the art, regardless of whether that person of ordinary skill in the art is an expert or an accused infringer. The Court's holding reflects a similar proposition by the Federal Circuit. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003)(explaining that "a

4. Howmedica's reliance on *SmithKline Beecham* is inapposite because the patent claims encompassed levels of a particular substance that could not be determined with technology available at the time. *Id.* at 1340. Although the patent described a very specific compound, crystalline paroxetine hydrochloride hemihydrate, the "district court considered the claim indefinite if construed to cover undetectable trace amounts of PHC hemihydrate." *Id.* The Federal Circuit disagreed because although a potential infringer had no way to measure the level of substance contained within its own product, the definite chemical structure claimed by the patent was clear. *Id.* at 1341.

claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not."). The Court found that "it is highly probable that a person of ordinary skill in the art would be unable to determine that 4 hours at 130°C is equivalent to 144 hours at 50° C." (Dkt. 176, June 13, 2007 Opinion, at 18.) The Court did not overlook or blur the legal standards between the law on claim construction, claim definiteness or infringement.

IV. CONCLUSION

Accordingly, the Court finds that Howmedica has failed to demonstrate that the Court overlooked any matter or controlling decision that would favor a grant of reconsideration. Howmedica's motion for reconsideration is denied.

October 30, 2007

/s/
United States Senior District Judge

APPENDIX D — ORDER OF THE UNITED STATES DISTRICT COURT, DISTRICT OF NEW JERSEY, FILED OCTOBER 30, 2007

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. No. 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.,

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

ORDER

Walls, Senior District Judge

It is on this 30th day of October 2007,

ORDERED that the plaintiff's motion for reconsideration of the Court's June 13, 2007 Order granting defendants Zimmer, Inc.'s, Zimmer Austin, Inc.'s, and Smith & Nephew, Inc.'s joint motion for summary judgment be and is hereby DENIED.

/s/
United States Senior District Judge

APPENDIX E — ORDER AMENDING THE APRIL 23, 2007 CLAIM CONSTRUCTION ORDER IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, DATED AUGUST 23, 2007

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Case No.: 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC. (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

THIS MATTER having been opened to the Court by way of joint motion by Plaintiff Howmedica Osteonics Corp. and Defendants Smith & Nephew, Inc., Zimmer, Inc., and Zimmer Austin, Inc., seeking entry of an Order amending this Court's April 23, 2007 Order on claim interpretation to correct inadvertent omissions; and good cause having been shown;

IT IS, this 23 day of August, 2007, hereby

Appendix E

ORDERED that the Parties' joint motion is GRANTED. Accordingly, the Court hereby amends its April 23, 3007 Order as follows:

- The term "annealed at temperature greater than 25°C," in claim 7 of the '020 patent shall be construed in the same manner as similar terms in claims 10, 11, and 12 of the '020 patent and claim 19 of the '814 patent, as set forth in Section II.B.4.b. of the April 23, 2007 Order;

- The term "method for treating ultra-high molecular weight polyethylene material . . . irradiating said material . . . and annealing said material" in claim 19 of the '814 patent shall be construed in the same manner as similar terms in claims 23 and 50 of the '934 patent, claim 7 of the '814, claims 12 and 24 of the '308 patent, and claims 1 and 6 of the '020 patent, as set forth in Section II.B.1.a of the April 23, 2007 Order; and

- The term "said layer of material is heated" as set forth in claim 10 of the '308 patent shall be construed in the same manner as similar terms in claims 1, 5, 12, 16, and 24 of the '308 patent, as set forth in Section II.B.4.a.iii. of the April 23, 2007 Order.

/s/_____
William H. Walls, U.S.D.J.

APPENDIX F — OPINION OF THE UNITED STATES DISTRICT COURT, DISTRICT OF NEW JERSEY, DATED JUNE 13, 2007

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. No. 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.,

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

OPINION

Walls, Senior District Judge

In this action brought by Howmedica Osteonics Corp. ("Howmedica") for infringement of four of its patents relating to medical implants, defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. move jointly for summary judgment on the issues of invalidity and non-infringement as to three of those patents. Defendants' motion for summary judgment on

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invalidity asks the Court to determine that numerous patent claims are invalid because they contain an equation term ("Arrhenius' equation") which is not amenable to definite construction by a person of ordinary skill in the art. Defendants' motion for summary judgment on non-infringement principally argues that Howmedica is foreclosed from proving infringement because it has not disclosed in discovery the precise manner in which defendants' products infringe its patents.

Having considered the parties' written submissions and oral arguments, the Court grants defendants' motion for summary judgment on invalidity. Accordingly, it will not address the motion for summary judgment on non-infringement.

FACTS AND PROCEDURAL HISTORY

A. Parties and Procedural History

Howmedica is a New Jersey corporation that manufactures and markets medical implants such as artificial knee and hip implants. Starting in 1993, Howmedica filed a series of related patents that disclose processes for irradiating and then heating polymers used in medical implants. The treatment increases the oxidation resistance of the polymer. A polymer with greater oxidation resistance retains its physical properties better, which makes it more suitable for use

in medical implants because it deteriorates more slowly in the body.

Defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. are also corporations in the business of manufacturing and marketing medical implants. In February 2005, Howmedica filed suit against defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants. These four patents are U.S. Patent No. 6,174,934 B1 (filed Jan. 23, 1998) ("the '934 Patent"); U.S. Patent No. 6,372,814 B1 (filed June 28, 2000) ("the '814 Patent"); U.S. Patent No. 6,664,308 B2 (filed Jan. 8, 2002) ("the '308 Patent"); U.S. Patent No. 6,818,020 B2 (filed June 13, 2003) ("the '020 Patent") (collectively, "the patents-in-suit"). Howmedica claims that four of the defendants' products, Longevity, Prolong, Durusul, and XLPE, infringe on these patents.

In January 2006, after considerable discovery, the parties filed reciprocal *Markman* motions requesting that the Court construct numerous patent claims. On July 27, 2006, defendants filed the present motion for summary judgment. The Court decided the *Markman* motions in April 2007. The parties argued the motion for summary judgment on May 15, 2006.

Defendants move for summary judgment on the issues of noninfringement and the invalidity of the

asserted claims of Howmedica's '934, '814, and '308 Patents. They argue that they are entitled to summary judgment on invalidity because the Howmedica patent claims at issue do not provide precise boundaries to the inventions they disclose. Defendants also seek summary judgment on non-infringement because Howmedica is unable to demonstrate how defendants' products infringe on these three patents. As said, the Court will not reach the issue of non-infringement because it finds the patents invalid.

B. The Invention

1. Background

Howmedica's patents describe a process for making medical implants from a polymer, typically ultra-high molecular weight polyethylene ("UHMWPE"), that has been irradiated and then heated. Irradiating and then heating the polymer in an oxygen-free environment for a defined period of time at a defined temperature will cause chemical reactions that make the polymer stronger by forming cross-links between polymer chains.

The initial irradiation of the polymer causes chemical bonds between sections of the polymer molecule to undergo scission (to split). Scission creates free radicals, or atoms and molecules which have unpaired electrons in their outermost electron shell. Free radicals are highly reactive because unpaired electrons in the outermost

shell allow an atom or molecule to form bonds more easily by sharing those electrons with other atoms or molecules.

The free radicals created by irradiating a polymer will react in two different ways. First, they will cause post-irradiation degradation of the polymer, i.e., further scission. Second, they will bond to one another and become inert. This latter process is called cross-linking. If the polymer is irradiated while exposed to oxygen, the free radicals will cause a significant amount of post-irradiation degradation of the polymer in comparison to the amount of cross linking. In contrast, if the polymer is irradiated in an inert atmosphere, more cross-linking and less post-irradiation degradation will occur. When the ratio of chain scission reactions to cross-linking reactions is lower, the polymer retains its qualities better over time. In other words, irradiating the polymer in an inert atmosphere creates a stronger material than irradiating it in oxygen.

2. Howmedica's Improvement on Prior Art

Howmedica cites two principal types of prior art in its patents. First, Howmedica cites patents that disclose irradiation of polymers (in the form of medical devices and otherwise) out of contact with oxygen to prevent post-irradiation oxidation. Second, Howmedica cites patents that describe heating processes which improve the physical characteristics of ultra-high molecular weight polyethylene.

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Howmedica's patent avowedly improves on prior art by disclosing a process whereby the polymer is irradiated and then heated for such a period of time that allows for a desired level of free radical cross-linking to occur. Both steps, irradiation and heating, take place out of contact with oxygen. Heating the polymer "helps free radicals . . . to migrate in the plastic matrix to meet other neighboring free radicals for cross-linking reactions." '934 Patent, 5:53-55. The patent specifications state that the post irradiation heating step has to be of a sufficient duration and temperature to reduce the number of free radicals "to a minimal or an accepted level." '934 Patent, 7:05-07.

3. Arrhenius' Equation

The '934, '814, and '308 Patent claims at issue in the motion for summary judgment all define the range of sufficient heating time and temperature combinations by referring to Arrhenius' equation. These claims state that the implant material is heated at a temperature and for a time at least equivalent to 50°C for 144 hours under Arrhenius' equation. Claim 23 of the '934 Patent is representative of these claims:

> A medical implant comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated to create free radicals in the absence of a free radical generation catalyst while out of contact with oxygen . . .

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> and then **heated** while out of contact with oxygen . . . **at a temperature of greater than 25°C for a sufficient time to create a level of cross-links between free radicals wherein the temperature and time are selected to be at least equivalent to heating said irradiated material at 50°C for 144 hours as defined by the Arrhennius' equation (14).**

'934 Patent, claim 23 (emphasis added).[1] In general, a chemical reaction will progress more quickly at a higher temperature, and more slowly at a lower temperature. Arrhenius' equation quantifies the relationship between the temperature at which a particular reaction occurs and the rate at which it proceeds. In the case of the invention described in Howmedica's claims, Arrhenius' equation is used to define the time and temperature required to achieve a particular amount of interlinking between free radicals in an irradiated polymer. This amount of interlinking is associated with a desirable level of oxidation resistance, resistance to solvents, durability, etc., for medical implants.

---

1. The following claims are at issue in this motion for summary judgment: claims 23, 27, 29, 50, and 52 of the '934 Patent; claims 7, 12, and 19 of the '814 Patent; and claims 1, 5, 10, 12, 16, 21, 23, and 24 of the '308 Patent. All of these claims either incorporate the Arhennius' equation term, or are dependent from claims that incorporate that term.

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The section of each patent's specification which discusses the preferred embodiment sets forth Arrhenius' equation. The '934 Patent specification is representative:

> In general, if a higher temperature is used, a shorter time period is required to achieve a prescribed level of oxidation resistance and cross-linking. In many cases, the relationship between the reaction temperature and the reaction rate follows the well-known Arrhennius [sic] equation:
>
> $$k_1 \text{ or } k_2 = A^* \exp(-\blacktriangle H/T) \qquad (14)$$
>
> where
>
> k_1 and k_2 are reaction rate constants from reactions 13
> A is a reaction dependent constant
> ▲H is activation energy of reaction
> T is absolute temperature (K)

934 Patent, 6:53-65. "Reactions 13," which are the source of the k_1 and k_2 terms in Arrhenius' equation in the specification, are also defined in the specification:

> [T]he rate of free radical reactions . . . increases with increasing temperature, according to the following general expressions:

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$$\frac{dr\cdot}{dt} = k_1[r\cdot] \text{ and } \frac{dP\cdot}{dt} = k_2[P\cdot] \qquad (13)$$

> Compared to room temperature, an elevated temperature not only increases the reaction rate constants, k_1 and k_2, but also helps free radicals r· and P· to migrate in the plastic matrix to meet other neighboring free radicals for cross-linking reactions.

'934 Patent, 5:43-55. Howmedica defines the terms r· and P· in the specification as "primary free radicals r·" and "secondary free radicals P·," both of which are produced through a series of reactions when a polymer is irradiated. '934 Patent, 2:56-57. Otherwise the terms of the "reactions 13" are not defined by the specification.

In its opposition to the motion to dismiss, Howmedica revises the equation set forth in the patents' specifications. Instead of defining Arrhenius' equation as it had initially, as equation 14 in the patent specifications, '934 Patent, 6:58, Howmedica now defines Arrhenius equation as:

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$$k_1 \text{ or } k_2 = A^*\exp(-\blacktriangle H/R^*T)^2$$

(Howmedica Opp'n at 11.) It explains the omission of "the gas constant R" from the specification as an "uncorrected typographical error."[3] *Id.*

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2. Dr. Stephen Li, in his expert declarations, represents the relationship of the Arrhenius' equation terms more clearly than the specification:

$$k = A^*\exp\left[\frac{-\blacktriangle H}{R^*T}\right]$$

(Decl. of Dr. Stephen Li, Aug. 24, 2006, ¶ 20.)

3. Howmedica states that the omission of the "gas constant 'R'" from the specification is of no consequence, since "[o]ne of the ordinary skill in the art understands that the Arrhennius [sic] equation includes the gas constant 'R'" as set forth in the revised equation. (Howmedica Opp'n at 11.) Howmedica supports this assertion with expert declarations and other evidence. (*See* Li Decl. ¶ 21; Decl. of William M. Risen, Jr., Aug. 24, 2006, Ex. 1 at 556.) Since defendants do not challenge Howmedica's assertion, the Court finds a person of ordinary skill in the art would understand the Arrhenius equation in the specification as containing a typographical error because the equation must include the "gas constant 'R.'" The Court construes the equation referenced in the claim to contain the gas constant. *See ISCO Int'l, Inc. v. Conductus, Inc.*, No. 01-587, 2003 WL 276250, at *5 (D. Del. Feb. 10, 2003) (disregarding typographical error clear to one skilled in art when construing claim); *Baily v. Dart Container Corp. of Michigan*, 157 F. Supp. 2d 110, 124 n.7 (D. Mass. 2001) (same).

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C. The Dispute

Defendants argue that Howmedica's patent claims are invalid because they are indefinite. They maintain that it is impossible for a person of ordinary skill in the art to apply the Arrhenius' equation term in the patent claims and so define the boundaries of the patent claims. Howmedica argues that the information contained in the specification is adequate for a person of ordinary skill in the art to derive the various Arrhenius' equation terms and determine whether her product infringes on Howmedica's.

LEGAL STANDARD

Defendants seek summary judgment on the ground that the asserted claims of '934, '814, and '308 Patents are invalid because they are indefinite. Summary judgment is appropriate when the moving party establishes that "there is no genuine issue as to any material fact and that [it] is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Whether a particular patent is "invalid for indefiniteness presents a question of law," *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001), because "claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Comm'ns, L.L.C. v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). Indefiniteness remains a matter of law, and the proper

province of the court, even when the determination of claim's indefiniteness depends on an underlying issue of fact. *Exxon*, 365 F.3d at 1376. In such circumstances the court will consider those underlying factual issues and rule on indefiniteness as a "matter of law on summary judgment." *Id.*

35 U.S.C. § 112 outlines the requirements for patent specifications and claims. That section states that for a patent claim to be valid, it must be definite:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The statute requires definiteness to foster invention; vague claims would deter inventors by confronting them with an undue risk of infringement. *See United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942) ("statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005) (quoting *United Carbon*).

According to the Federal Circuit, a claim is sufficiently definite to satisfy section 112 "[i]f one skilled

in the art would understand the bounds of the claim when read in light of the specification." *Miles Labs., Inc., v. Shandon, Inc.*, 997 F.2d 870 (Fed. Cir. 1993). Courts do not demand absolute clarity from valid patents; they only require "that the claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite." *Exxon*, 265 F.3d at 1375.

The level of precision demanded from a patent claim depends on the patent's subject matter and its relationship to prior art. A patent claim's principal function is to distinguish the claimed invention from prior art. *United Carbon*, 317 U.S. at 236. This means that when similar prior art does not exist or the subject matter does not allow for great precision, there is some leeway for ambiguity in claim terms. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985) ("amount of detail required to be included in claims depends on the particular invention and the prior art" and claim language should be "as precise as the subject matter permits"). However, when claim terms serve to distinguish the invention from close prior art, they must be amenable to more definite construction if possible. *See Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 453 (Fed. Cir. 1985); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991). In *Amgen* the Federal Circuit held invalid a patent claim that disclosed "[h]omogeneous erythropoietin

characterized by . . . a specific activity of at least about 160,000 IU per absorbance unit at 280 nanometers." 927 F.2d at 1203; U.S. Patent 4,677,195, claim 4 (filed Jan 11, 1985). The Federal Circuit reasoned that the phrase "characterized by . . . a specific activity of at least about 160,000 IU per absorbance unit" was indefinite because prior art disclosed an urinary erythropoietin product with specific activity of 128,620 IU per absorbence unit. *Amgen*, 927 F.2d at 1217-18. A person of ordinary skill in the art would find the claim indefinite because it did not "permit one to know what specific activity values below 160,000, if any, might constitute infringement." *Id.* at 1217.

For any patent approved by the Patent Office, there is a "statutory presumption of validity." *Exxon*, 265 F.3d at 1375. This means that the burden of proving a patent's invalidity rests with the party that challenges its validity. *See* 35 U.S.C. § 282. To meet that burden, the party challenging validity bears the burden of proving, by clear and convincing evidence, that the invention fails to meet the requirements of patentability. *See Hewlett-Packard Co. v. Bausch & Lomb*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the truth of [the] factual contentions [is] 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

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DISCUSSION

The dispute between the parties focuses on the Arrhenius' equation term in the patent claims. The term serves to define the scope of the patent by disclosing to a potential infringer whether her product trespasses onto the range of heating times and temperatures disclosed by the patent. If a potential infringer is unable to apply the Arrhenius' equation term, she will not be able to determine the scope of Howmedica's invention and will be confronted by an undue risk of infringement. *See United Carbon*, 317 U.S. at 236. The nature of the subject matter addressed by the Arrhenius' equation claim term, which purports to define an exact minimum time period for heating the polymer at any given temperature, suggests that the Court should require that the term be construable with a relatively high degree of precision.

Moreover, the prosecution history of the '934 Patent demonstrates that the Arrhenius' equation term in the patent claim serves to distinguish Howmedica's invention disclosed by the claims at issue from prior art. Howmedica's initial application discloses an irradiated polymer "heated at a temperature of greater than 25°C to create cross-links between free radicals." (Decl. of Imron T. Aly, July 21, 2006, Ex. 4, Patent App. 09/012,345, dated Jan. 23, 1998, at 20.) The claims in that application contained no further restrictions on the time and temperature combinations that could be used. The

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patent examiner rejected the proposed claims under 28 U.S.C. 102(b) because prior art anticipated the disclosed invention. The examiner cited Robert M. Streicher's "Investigation on Sterilization and Modification of High Molecular Weight Polyethylenes by Ionizing Radiation" ("Streicher 1989") which had disclosed annealing ultra-high molecular weight polyethylene "for two hours at temperature from 40 C to 80 C" after irradiation. (Aly Decl. Ex. 5, PTO Office Communication, dated Sept. 4, 1999, at 2-3. *See also* Aly Decl. Ex. 8, Streicher 1989, at 35.)

To save its patent, Howmedica narrowed its the claimed invention by limiting its claim to avoid prior art. It did this by including the Arrhenius' equation term in its patent:

> In order to distinguish the present embodiment of the invention over Streicher 1989, applicant has amended the claims . . . . Thus, the claims contemplate that the material is . . . annealed to form cross-links between free radicals at any time-temperature equivalency (as determined by Arrhenius' equation) that is at least the same as heating . . . [the] material to 50°C for 144 hours.

(Aly Decl. Ex. 6, Response to Office Action, dated Dec. 9, 1999, at 7.) Since Howmedica expressly resorted to the Arrhenius' equation term to distinguish the

invention disclosed by '934 Patent from similar prior art, the term must be susceptible to more definite interpretation than otherwise. *See Amgen*, 927 F.2d at 1218. Otherwise, the claim would not "clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise." *United Carbon*, 317 U.S. at 236.

To show that the Arrhenius' equation term is not amenable to definite interpretation, defendants initially point to the multiple undefined variables in the equation as set forth in the specification and various statements in the record. They argue that a person of ordinary skill in the art, confronted by the patent claims and specifications, would be unable to apply Arrhenius' equation to determine whether heating the polymer for any given time at a certain temperature is equivalent to heating the polymer for 144 hours at 50°C. That person could not determine from the patents, defendants argue, whether her product infringes on Howmedica's.

Howmedica responds by setting forth a single method for interpreting the Arrhenius' equation term. This method requires that a person of ordinary skill in the art identify two equivalent time/temperature pairs from the patent. Once she has identified the two equivalent pairs, the person can derive the various unknown terms in Arrhenius' equation as presented in the specification. Then, having filled in the various

unknown terms, she can easily calculate the boundaries of the patent. In other words, if a person knows that heating the polymer for 144 hours at 50°C will allow for the same level of cross linking and elimination of free radicals as heating the polymer for X hours at Y°C, then the remaining terms of the equation may be determined. According to Howmedica, a person of ordinary skill in the art could indentify from the patent claims and specifications two equivalent time and temperature pairs, derive the necessary Arrhenius' equation variables, and then apply the resulting equation to determine the period required at a given temperature, and vice versa.

As factual support for its assertion, Howmedica submits two expert declarations. The first is by Dr. William M. Risen, Jr., Ph.D, a Professor of Chemistry at Brown University. (Decl. of William M. Risen, Jr., Aug. 24, 2006.) The second is by Dr. Stephen Li, Ph.D., president of Medical Device Testing and Innovations, LLC. (Decl. of Dr. Stephen Li, Aug. 24, 2006.) Dr. Li received his Ph.D in Chemistry from the University of Southern California in 1977. Defendants' did not contest the experts' qualifications in their papers or at oral argument.

Both Dr. Li and Dr. Risen begin by stating that heating the polymer for 144 hours at 50°C and for 4 hours at 130°C are equivalent time and temperature pairs. Dr. Risen reasons:

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> In US 6,174,934 B1, the inventors described a type of material obtained, in part, by heating an irradiated ultra-high molecular weight polyethylene under conditions of time and temperature designed to create crosslinks and reduce free radicals. They claim that the post-irradiation heating must be done in a way that is at least equivalent to heating it for 144 hours at 50°C. Thus, this is the minimum heating time specified at 50°C. The minimum heating time at a higher temperature is given as 4 hours at the high end of the range, which leads to a minimum annealing time of 130°C.

(Risen Decl. ¶ 14.) Dr. Li expressly asserts that a person of ordinary skill in the art would interpret the specification and claims to disclose that heating the material for 144 hours at 50°C is equivalent to heating it for 4 hours at 130°C:

> [I]t is my opinion that one of ordinary skill in the art would read the specification of the patents in suit to teach that heating irradiated UHMWPE material at 130° for 4 hours or heating irradiated UHMWPE material at 50 C for 144 hours would provide UHMWPE with a sufficient number of crosslinks to be in accordance with the invention disclosed in the specifiation of the patents in suit.

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(Li Decl. ¶ 27.)

Drs. Lee and Risen then methodically explain how, through a series of calculations, a person of ordinary skill in the art would apply the equation using the two time/temperature pairs. In brief, she would use the "two time/temperature heating combinations" to "calculate the activation energy ▲H to be used in in the Arrhenius equation in order to calculate additional time/temperature heating combinations that are equivalent to heating UHMWPE material at 50 C for 144." (Li Decl. ¶ 30.)

Dr. Li, when deposed in July 2006, confirmed that Howmedica's entire argument that the Arrhenius' equation term is amenable to construction depends on the assumption that heating the polymer for 144 hours at 50°C is equivalent to heating it for 4 hours at 130°C:

> Q. Okay. I take it that the accuracy of any calculations made in that way would depend on you being correct about 130 C at four hours being the equivalent to 50 C at 144 hours, right?
>
> A. They would both have to get you to the same material property or material description that they want you to get to, yes.

(Certification of Jason S. Oliver, Aug. 28, 2006, Ex. D 107:3-9.) Dr. Li's response is in accord with the method

by which he and Dr. Risen apply Arrhenius' equation in their declarations. Neither Dr. Li nor Dr. Risen suggest that there exists any method for applying the Arrhenius' equation term that does not depend on identifying two equivalent time/temperature pairs.[4]

Howmedica bases its assumption that 4 hours at 130°C is equivalent to 144 hours at 50°C on a single passage of the '934 Patent's specification:

> In general, the desired elevated temperature is between the room temperature and the melting point of the polymer. For UHMWPE, this temperature range is between about 25°C and about 140°C. However, the preferred annealing temperature range is from about 37°C to about 135°C. The preferred time and temperature is 130°C for 20 hours with the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range).

4. In an earlier declaration, submitted in support of Howmedica's claim construction, Dr. Li suggested that the Arrhenius' equation term could be reduced to a rule of thumb. According to this rule, for every 10°C increase in temperature the time required is halved. (Aly Decl. Ex. 36 ¶ 21.) Dr. Li's current testimony contradicts his rule of thumb. As example, in the present declaration Dr. Li claims that if the heating temperature is raised from 120°C to 130°C, the time required decreases from 5.8 hours to 4 hours, not 2.9 hours. (Li Decl. ¶ 34.)

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'934 Patent, 5:57-63. From the evidence it appears that this passage is the sole support for the claim that 4 hours at 130°C is equivalent to 144 hours at 50°C. The Li and Risen Declarations clearly refer to this passage as the basis for indentifying 4 hours at 130°C as one of the pairs. Aside from this passage, Dr. Li and Risen cite no other basis for their assumption that heating the polymer for 4 hours at 130°C is equivalent to heating it for 144 hours at 50°C. Moreover, they never assert that heating the polymer for 4 hours at 130°C *in fact* achieves the same level of cross-linking as heating it for 144 hours at 50°C. At oral argument, Howmedica's counsel was also only able to point to this one passage of the specifications when the Court asked him to explain how person of ordinary skill in the art could determine the two equivalent time/temperature pairs.

According to counsel, a person of ordinary skill in the art would interpret "preferred time and temperature is 130°C for 20 hours with the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range)" to mean that the minimum required time is 4 hours at 130°C. But the passage only states that the minimum annealing time is four hours at the "high end of the range," and mentions two ranges: the UHMWPE "temperature range" ("between about 25°C and about 140°C") and the "preferred annealing

temperature range" ("from about 37°C to about 135°C").[5] Nowhere in the specification is 130°C described as at "the high end of the range." Neither counsel nor Howmedica's experts can provide any reason for their belief that a person of ordinary skill in the art would pair 4 hours with 130°C, rather than 135°C or 140°C.

The Court is not also not convinced that a person of ordinary skill in the art, even if she determined that the passage identified 4 hours at 130°C as a time/temperature pair, would believe that pair to be equivalent to 144 hours at 50°C. First, the specification passage that describes heating the polymer for "130°C for 20 hours with the minimum annealing time being about 4 hours" concerns pre-irradiation heating. In contrast, "50°C for 144 hours" in the patent claims describes post-irradiation heating. Howmedica, Dr. Risen, and Dr. Li do not explain or state that the pre-irradiation heating times are relevant or equivalent to the post irradiation heating time. In other words, there is no argument made that heating the polymer for 144 hours at 50°C after it has been irradiated is equivalent to heating it for 4 hours at 130°C before irradiation.

5. Dr. Li, in his deposition testimony, agreed with the statement that "140 degrees C is the high end of the range disclosed in the patent." (Supplemental Certification of Jason S. Oliver, Sept. 11, 2006, Ex. H 96:23-97:02.) He also agreed that it was possible that the temperature range in the '308 Patent would potentially "go up to, say, 200 degrees C." *Id.* at 98:11-99:06. It is quite unclear to the Court how Dr. Li can now assert in his declaration that a person of ordinary skill in the art would interpret "a temperature at the high end of the range" to mean 130°C.

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Second, 144 hours (at 50°C) is a preferable heating time, but 4 hours (at 130°C, 135°C, or 140°C) is a minimum time. The specification expressly only describes 144 hours at 50°C as a preferable time, never as a minimum time: "[i]n general, the implant is heated for at least 48 hours at a temperature of about 37 to 70°C and preferably for 144 hours at 50°C." '934 Patent, 4:44-46. Similarly, the specification also identifies *20* hours as the preferred time at 130°C: the "preferred time and temperature is 130°C for 20 hours." '934 Patent, 5:60-61. In contrast, that passage describes 4 hours as the "minimum annealing time." '934 Patent, 5:61-62.

In short, neither Howmedica nor its experts provide any basis for assuming that 4 hours at 130°C is equivalent to 144 hours at 50°C. Defendants have demonstrated that the passage of the specification that Howmedica relied upon is ambiguous, is irrelevant to post-irradiation heating, and even contradicts Howmedica's experts' position. Defendants have proven, by the defects in Howmedica's evidence and by the statements of Howmedica's own experts, that it is highly probable that a person of ordinary skill in the art would be unable to determine that 4 hours at 130°C is equivalent to 144 hours at 50°C.

Contrary to Howmedica's assertions, the specification discloses at least three time/temperature pairs that *could* be equivalent to 144 hours at 50°C, the first being the most plausible: (1) 20 hours at 130°C, (2)

4 hours at 140°C, and (3) 4 hours at 135°C. If a person of ordinary skill in the art assumes that any one of these three alternatives is equivalent to 144 hours at 50°C, she will arrive at an entirely different interpretation of the scope of Howmedica's patents from that proposed by Howmedica's experts. Because a person of ordinary skill in the art would not be able to discern whether a competitor's similar product actually infringes on Howmedica's patents, the Court finds the claim indefinite.

CONCLUSION

Defendants have proven by clear and convincing evidence that the Arrhenius' equation terms in the '934, '814, and '308 Patents are insolubly ambiguous. Accordingly, the Court finds the '934, '814, and '308 patent claims at issue invalid and grants summary judgment to defendants on this ground. Since the Court has found that the '934, '814, and '308 Patent claims at issue are indefinite, the Court will not consider the defendants' motion for summary judgment on non-infringement. An appropriate order will issue.

June 13, 2007

/s/
William H. Walls
United States Senior District Judge

APPENDIX G — ORDER OF THE UNITED STATES DISTRICT COURT, DISTRICT OF NEW JERSEY FILED JUNE 13, 2007

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. No. 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.,

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

ORDER

Walls, Senior District Judge

It is on this 13th day of June 2007,

ORDERED that the defendants' joint motion for summary judgment on the invalidity of the asserted claims of the '934, '814, and '318 Patents be and hereby is GRANTED

s/
United States Senior District Judge

APPENDIX H — OPINION OF THE UNITED STATES DISTRICT COURT, DISTRICT OF NEW JERSEY, FILED APRIL 23, 2007

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. No. 05-897 (WHW)

HOWMEDICA OSTEONICS CORP.,

Plaintiff,

v.

ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,

Defendants.

OPINION

Walls, Senior District Judge

Before the Court are plaintiff Howmedica Osteonics Corp.'s ("Howmedica") and defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc.'s motions for claim construction. Defendants also move to strike Dr. Stephen Li's affidavits in support of Howmedica's claim interpretation and Howmedica's supplementary filing of November 13, 2006. Pursuant to Fed. R. Civ. P. 78, the motions are decided without oral arguments.

Appendix H

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I. FACTS AND PROCEDURAL BACKGROUND

Howmedica, a New Jersey corporation with its principal place of business in Mahwah, New Jersey, manufactures and markets medical implants such as artificial knee and hip implants. Beginning in 1993, Howmedica filed a series of related patents that describe processes for heating and irradiating polymers used in medical implants. *See* U.S. Patent No. 5, 414,049 (filed Jun. 1, 1993) ("the '049 Patent"); U.S. Patent No. 5,650,485 (filed Oct. 7, 1994) ("the '485 Patent"); U.S. Patent No. 5,543,471 (filed Mar. 15, 1995) ("the '471 Patent")[1]; U.S. Patent No. 5,728,748 (filed Oct. 16, 1996) ("the '748 Patent"); U.S. Patent No. 6,174,934 B1 (filed Jan. 23, 1998) ("the '934 Patent"); U.S. Patent No. 6,372,814 B1 (filed Jun. 28, 2000) ("the '814 Patent"); U.S. Patent No. 6,664,308 B2 (filed Jan. 8, 2002) ("the '308 Patent"); U.S. Patent No. 6,818,020 B2 (filed Jun. 13, 2003) ("the '020 Patent"). The heating processes described in the patents increase the oxidation resistance of medical implants by causing cross-links to form between free radicals produced by the polymer's irradiation. Greater oxidation resistance enables a polymer better to retain its physical properties, making it more suitable for use in medical implants.

1. The '471 Patent is a divisional patent of the original '049 Patent. The four patents asserted by Howmedica here are continuation applications of the '485 Patent, not the '471 Patent.

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Defendants are also corporations that manufacture and market medical implants. In February 2005, Howmedica filed suit against defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants: the '934, '814, '308, and '020 Patents (the "patents-in-suit").

After a period of discovery, the parties moved forward in their litigation. In January 2006, they filed reciprocal *Markman* motions requesting the Court construe numerous patent claims. In February 2006, defendants filed a motion to exclude affidavits of Howmedica's expert, Dr. Stephen Li, that Howmedica had attached as exhibits to its claim interpretation memoranda. In August 2006, defendants filed a supplemental claim interpretation brief. In November 2006, the Court asked the parties to file additional papers stating which patent claims were potentially at issue and clarifying which terms in those claims required construction. After the parties had filed these supplemental papers, defendants moved to strike Howmedica's clarification. The Court will address each motion in turn.

II. CLAIM CONSTRUCTION

A. STANDARD

Claim construction is a matter of law reserved exclusively for the courts. *Markman v. Westview*

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Instruments, Inc., 517 U.S. 370 (1996). The claims of the patent-in-suit must be construed before an infringement or invalidity analysis can be performed. *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1315 (Fed. Cir. 1998); *Helfix, Ltd.v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000). Only those claims at issue and in dispute need to be construed. *See United States Surgical Corp. v. Ethicon*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

When interpreting an asserted patent claim, courts should look first to the intrinsic evidence of record, which includes the patent's claims, the patent's specification, and the complete prosecution history. *Markman*, 52 F.3d at 979. Intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The first principle of claim construction is that "the language of the claim defines the scope of the protected invention." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 619-20 (Fed. Cir. 1995) (citing *Yale Lock Mfg. Co. v. Greenleaf*, 117 U.S. 554, 559 (1886). Accordingly, "resort must be had in the first instance to the words of the claim," words to which courts generally ascribe their ordinary meaning. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759 (Fed. Cir. 1984). A term's ordinary meaning is the accustomed technical "meaning that the term would have to a person of

ordinary skill in the art in question at the time of the invention." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Claim terms are assigned their ordinary meaning unless it appears from the patent specification or file history that the words were used differently by the inventor. *See id.* at 1313, 1316-17.

Phillips observed that often "the claims themselves provide substantial guidance as to the meaning of particular claim terms." 415 F.3d at 1314. Both "the context in which a term is used in the asserted claim" and the "[o]ther claims of the patent in question" are useful for understanding the meaning of claim terms. *Id.* Similarities and differences among various claims are useful for understanding the meaning of particular claim terms. *Id.* As example, the "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation is not present in the independent claim." *Id.* at 1314-15 (citing *Liebel Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)).[2]

2. This direction from the Federal Circuit is one form of what is called *claim differentiation*, the doctrine that claims should be interpreted to have distinct scopes. The doctrine of claim differentiation is not an absolute doctrine, since clear limitations in the specification may trump a claim's interpretation under claim differentiation. Claim differentiation is most controlling as a hermeneutic aid when a court interprets the relationship between independent and dependent claims because the Patent Act instructs that

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The specification is also highly relevant to the claim construction analysis, especially "when the claim language itself lacks sufficient clarity to ascertain the scope of the claims." *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003) (cited in *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005)). Often "'it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Patent claims "must be read in view of the specification, of which they are a part. . . . For claim construction purposes, the [specification's] description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979-80. *See United States v. Adams*, 383 U.S. 39, 49 (1966); *Mycogen Plant Science v. Monsanto Co.*, 243 F.3d 1316, 1327 (Fed. Cir. 2001); *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Thus, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

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dependent claims "shall contain a reference to a claim previously set forth and *then specify a further limitation of the subject matter claimed.*" 35 U.S.C. § 112 (emphasis added). *See Curtiss Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

However, in *Comark Commc'ns Inc. v. Harris Corp.*, the Federal Circuit cautioned that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitiation into the claim from the specification." 156 F.3d 1182, 1186-87 (Fed. Cir. 1998). If the specification expressly or implicitly defines terms used in the claims differently from their ordinary meaning, then the definition derived from the specification will govern how the claim terms are to be interpreted. *Markman*, 52 F.3d at 979-80. If the embodiments in the specifications are intended to be exemplary, and not "strictly coextensive" with the claims, then they should not be read to limit the claims. *See Phillips*, 415 F.3d at 1324; *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1346 (Fed. Cir. 1999); *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

The prosecution history may also aid courts when they construe patent claims. It may demonstrate "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. If the inventor cites and acquiesces to prior art, this is a good indication of where he understood his claims to begin and end. *Autogiro Co. of Am. v. United States*, 384 F.2d 391 (1967) (cited in *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1368 (Fed. Cir. 2004)). If the inventor "unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution

disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (quoted in *Liquid Dynamics*, 355 F.3d at 1367-68). When an ancestor patent and the patent-in-suit share common claim terms, narrowing disclaimers made during the ancestor patent's prosecution may narrow as well the scope of the common claim terms in the subsequent patent-in-suit. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305-06 (Fed. Cir. 2001). *See Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1300 (Fed.Cir.1999) ("[P]rosecution of a parent application may limit the scope of a later application using the same claim term.").

Courts may also rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. In particular, technical dictionaries have been recognized as a "tool[] that can assist the court in determining the meaning of particular terminology." *Phillips*, 415 F.3d at 1318 (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). However, extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted).

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B. ANALYSIS

Howmedica asserts that defendants have infringed twenty-five of its claims. The parties dispute the construction of twelve independent and ten dependent claims.[3] The parties have exhaustively briefed their dispute, indentifying numerous discreet terms and phrases whose meaning they dispute. Beyond their disagreement on the meaning of various terms, the parties also contest which words and phrases are in dispute.

Fundamentally, Howmedica and defendants dispute the role the patents' specifications should play in interpreting the language of the disputed claims. Howmedica argues that the Court should not import the relatively narrow scope of the invention described by the specification to limit broad claim language. Defendants maintain that the specifications should narrow the scope of facially broad claim language because the specifications implicitly define the disputed claim terms. Ultimately, defendants seek to limit the invention disclosed by the patents-in-suit to the invention described by the preferred embodiment

3. Howmedica asserts claims 23, 27, 29, 50, and 52 of the '934 Patent; claims 7, 12, and 19 of the '814 Patent; claims 1, 5, 10, 12, 16, 21, 23, and 24 of the '308 Patent; and claims 1, 2, 3, 5, 6, 7, 10, 11, and 12 of the '020 Patent. Howmedica does not ask the Court to construe claims 5 and 16 of the '308 Patent or claim 5 of the '020 Patent.

contained in the specifications: a formed and machined polymer implant is put in a package, oxygen is removed from that package, the package is sealed, the package is radiation sterilized and then heated. *See, e.g.*, '934 Patent 6:06-7:38.

In large part, the Court adopts Howmedica's view that defendants seek to improperly import limitations from the specification into the claims. Defendants do not just ask the Court to define claim terms with reference to the specification; they ask the Court to re-draft the disputed claims on the basis of the specification. This is not the task of claim construction.

For economy, the Court will categorize the claims under consideration in this opinion by each issue the parties dispute. Then the Court will determine how each claim should be interpreted with respect to each disputed issue.

With specific exceptions, the Court rejects defendants' arguments that the patent claims at issue require that: (1) the finished orthopedic implant, not constituent polymer material, be irradiated and heated; (2) the irradiation must serve to sterilize the implant; (3) the medical implant must be irradiated and heated after it has been placed in its packaging; and (4) the heating process must have an upper limit of 140° C. To read these claims terms as defendants propose, the Court would have to impermissibly import limitations

from the specifications into the claims. The claims, whose language the patent examiners approved, are unambiguously broader than the particular embodiments of the invention described by the specifications. Therefore, the Court interprets the specifications to be more exemplary than coextensive of the claims. *See Phillips*, 415 F.3d at 1324. The prosecution history highlighted by defendants does not convince the Court that Howmedica facilitated the patents' prosecution by limiting the scope of the disputed claim terms, because the ancestor claims' terms differ from the disputed terms.

The Court accepts defendants' arguments that the minimum time and temperature for which the polymer is heated is described by the relationship established by Arrhenius' equation, in those claims which refer to that equation. With respect to the construction of the term "oxidation index" in the '020 Patent, the Court adopts the definition of the term contained in that patent's specification, largely as proposed by defendants.

1. ***Irradiation and Heating of Polymer/ Implant***

Defendants contend that the disputed patent claims require that only finished orthopedic components be heated and irradiated. Howmedica argues that the claims also allow for heating and irradiation of pre-formed polymer materials. The Court discerns that this

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issue potentially arises in all twelve of the independent claims at issue:

> '934 Patent, claim 23: "medical implant comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated . . . and then heated"
>
> '934 Patent, claim 50: "medical implant comprising a formed olefinic material . . . , said material irradiated . . . and then heated"
>
> '814 Patent, claim 7: "device comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated . . . and then heated"
>
> '308 Patent, claim 1: "method of treatment for the ultra-high molecular weight polyethylene material forming a medical implant . . . comprising . . . irradiating . . . and heating the polyethylene material forming the implant"
>
> '308 Patent, claim 12: "method for processing ultra-high molecular weight polyethylene . . . comprising . . . irradiating . . . and heating the polymer"
>
> '308 Patent, claim 24: "medical implant comprising . . . an ultra-high molecular weight

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> polyethylene material . . . , said material . . . which has been irradiated . . . and then heated"
>
> '020 Patent claim 1, 6: "medical implant comprising an irradiated ultra-high molecular weight polyethylene"
>
> '020 Patent, claims 7, 10, 11, 12: "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed"

Defendants argue that the scope of the above claims should be limited to medical implants or devices, which are irradiated and heated *after* they have been formed and/or machined. Howmedica argues that these claims also encompass processes whereby a polyethylene material is irradiated and heated before it is formed and/or machined into a medical implant.

Howmedica relies upon the language of the patent claims for its interpretation. Defendants support their construction by arguing that the four patents' specifications limit the patent claims. Because the specifications only expressly set forth a process whereby fully finished orthopedic components are irradiated and heated, defendants maintain that the claims should be limited to that process.

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a. '934 Patent, claims 23, 50; '814 Patent, claim 7; '308 Patent, claims 12, 24; '020 Patent, claims 1, 6

Claims 23 and 50 of the '934 Patent, claim 7 of the '814 Patent, claims 12 and 24 of the '308 Patent, and claims 1 and 6 of the '020 Patent clearly and unambiguously contemplate irradiation and heating before final forming and machining of the implant. The Courts interprets each of these claims by looking towards its ordinary meaning, grammar, syntax, and context. To narrowly construe these claims, whose language unequivocally establishes their meaning, would be to commit the "cardinal sin" of claim construction: to import limitations from the specification into the claim. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). In contrast, the express language of claim 1 of the '308 Patent clearly limits that claim to irradiation and heating of finally formed medical implants.

Claims 23 and 50 of the '934 Patent, claim 7 of the '814 Patent, and claim 24 of the '308 Patent all distinguish between (1) the "implant" or "device" and (2) the "material." These four claims unambiguously refer to the irradiation and heating of "said material"; they do not refer to the treatment of the "implant" or "device." Had the inventor intended to limit the scope of these claims to the heat and radiation treatment of "finished orthopedic implants," he would have stated

that the implant, not the "material," was to be irradiated and heated. The Court reads these claims to include the treatment of the constituent polyethylene material *before* it has been formed and machined into its final form as an implant.

Claim 12 of the '308 Patent expressly states that it is for a "method of processing . . . polyethylene." Never does claim 12 refer to processing a medical implant, finished or unfinished. It clearly describes a method of heating and irradiating a "polymer," and is not limited to the treatment of finished implants.[4]

Claims 1 and 6 of the '020 Patent refer to a medical implant comprised of "an irradiated ultra-high molecular weight polyethylene." The Court finds that this claim clearly expresses that the polyethylene is irradiated, and imposes no requirement that the irradiation step occur after the medical implant has been finished.

b. '308 Patent, claim 1

In constrast, the Court finds that claim 1 of the '308 Patent is limited to irradiation and heating of a finished implant, because it is for "irradiating . . . and heating

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4. This is especially clear when the language of claim 12 of the '308 Patent is juxtaposed with claim 1 of that Patent, which is so limited. *See infra*.

the polyethylene material forming the implant." Claim 1 clearly contemplates that the polyethylene material has already been formed into an implant *before* it is irradiated and heated. The Court's interpretation is bolstered by comparing claim 1 to claim 12 of the '308 Patent, which describes a process identical to that described by claim 1 – except that it refers to the irradiation of the "polymer" and not the finished implant.[5]

c. '020 Patent, claims 7, 10, 11, 12

Unlike the '934, '814, '308, and '020 Patent claims discussed above, claims 7, 10, 11, and 12 of the '020 Patent are ambiguously phrased. These latter claims describe a "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed." It is not grammatically clear if these claims could involve irradiating and heating the polyethylene material, or if they are limited to treating finished implants made of the material. From the claims alone, the Court cannot discern whether the "medical implant" or the

5. Unless otherwise stated, the dependent claims at issue are construed in accord with this opinion's reading of the respective independent claims. As example, claims 27, 29, and 52 of the '934 Patent, claim 12 of the '814 Patent, claims 21 and 23 of the '308 Patent, and claims 2, 3, and 5 of the '020 Patent are not limited to the processing of finished implants. Dependent claim 10 of the '308 Patent is limited to the irradiation and heating of the finished implant.

"polyethylene" are modified by the term "irradiated and annealed."

Faced by ambiguous claim language, the Court looks to the context of these claims. The Court has already determined that claims 1 and 6 of the '020 Patent do not require that only the finished implant may be irradiated. *See supra*. Claims 7, 10, 11, and 12 are clearly intended to parallel claims 1 and 6, which the Court has construed to disclose heat and radiation treatment of both the polymer and finished implants. Notably, claims 7, 10, 11, and 12 include an annealing (heating) step that makes their grammar and syntax more ambiguous. As example, claim 1 describes a "medical implant comprising an irradiated ultra-high molecular weight polyethylene," while claim 7 describes a "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed." Since the only material difference between the two sets of claims is the annealing step, the Court interprets claims 7, 10, 11, and 12 of the '020 Patent consistently with claims 1 and 6. Claims 7, 10, 11, and 12 of the '020 Patent are not limited to the irradiation and annealing of finished implants.

d. Prosecution History

The Court finds unconvincing the Defendants' reference to the prosecution of the '049, '748 and '020 Patents. Defendants seek to limit terms of the patents-in-suit by pointing to limitations made during the course

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of the prosecution of the '049 Patent, an ancestor patent of the patents-in-suit. Unlike the '934, '814, '308, and '020 Patents, all of the '049 Patent's claims clearly describe a process whereby a finished implant is irradiated and heated. The '049 Patent does not share the relevant claim terms with the patents-in-suit. *See Advanced Cardiovascular*, 265 F.3d at 1305-06. As example, a typical claim of the '049 Patent states:

> A method for producing a medical implant . . . comprising the steps of:
>
> > sealing the implant in an oxygen impermeable package . . . ; and
> >
> > radiation sterilizing the said packaged implant; and
> >
> > heating said packaged implant . . . at a temperature of between about 37 C and the melting point of [the] olefenic material . . . .[6]

'049 Patent, claim 1. Unlike the patents disputed here, all the '049 Patent claims clearly and unambiguously

6. All of the independent claim in the '049 Patent are similar in that they expressly describe irradiating and heating a finished, packaged implant. '049 Patent, claims 1, 12, 19, 25, 31, 36.

refer to a process where the *finished, packaged implant* is irradiated and heated. The Court will not limit the scope of the descendant patents on the basis of representations made during the prosecution of the ancestor patents, when the ancestor patent's claims differ so materially from those of the descendant patent.

Defendants also cite Howmedica's communications to the examiner during its prosecution of the '020 and '748 Patents. Neither of these statements is particularly relevant here. At the examiner's request, Howmedica cancelled certain patent claims "directed to an ultra-high molecular weight polyethylene." (*See* Defs.' Exs. J, K.) Contrary to defendants' assertions, Howmedica's did not restrict the invention to irradiation and heat treatment of formed medical implants. The '748 Patent prosecution statements to which defendants point, which sought to distinguish that patent from prior art, are not properly characterized as disclaimers. (*See* Defs.' Ex. N.) By no means do they clearly disclaim the treatment of the polymer before it is formed.

2. *Construction of "Irradiate"*

Defendants argue that the irradiation step described in the patent claims at issue requires irradiation for the purposes of sterilization. Howmedica argues that the irradiation step may also include irradiation which is not for the purposes of sterilization.

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> *'934 Patent, claims 23, 50; '814 Patent, claim 7*: "said material irradiated to create free radicals"
>
> *'814 Patent, claim 19*: "irradiating said material . . . to create free radicals"
>
> *'308 Patent, claim 1*: "irradiating the polyethylene material forming said implant to create free radicals"
>
> *'308 Patent, claim 12*: "creating free radicals in the polymer chain by irradiating the ultrahigh molecular weight polyethylene material"
>
> *'308 Patent, claim 24*: "said material . . . which has been irradiated to create free radicals"
>
> *'020 Patent, claims 1, 6*: "irradiated ultra-high molecular weight polyethylene"
>
> *'020 Patent, claims 7, 10, 11, 12*: "ultra-high molecular weight polyethylene . . . irradiated"

Howmedica proposes that "irradiated" means "is exposed to radiation, including but not limited to gamma ray, x-ray or electron beam radiation." Defendants propose that the term "irradiated" means "sterilization irradiated, *i.e.* exposed to radiation for purposes of

sterilization." Defendants seek to narrow the term's meaning by referring to the predominant (but not exclusive) usage of the term irradiation in the specifications: irradiation "for purposes of sterilization." The Court rejects defendants' argument.

a. '934 Patent, claims 23, 50; '814 Patent, claims 7, 19; '308 Patent, claims 1, 12, 24

The ordinary meaning of the term "irradiate," without modification, does not inherently connote "irradiate for the purpose of sterilization." Irradiate means to expose to radiation, plain and simple.

Express limitations in related dependent claims also do not support defendants' narrow definition of the term "irradiated" in claims 23 and 50 of the '934 Patent. Dependent claim 28 of the '934 expressly limits independent claim 23 to radiation treatment of sufficient strength and type to sterilize the polymer: it is for "[t]he medical implant as set forth in claim 23 wherein the irradiation is a high energy beam of a dose capable of killing bacteria, viruses, or other microbial species." '934 Patent, claim 28. The limitation in the dependent claim strongly implies that "irradiated" in claim 23 includes exposure to radiation insufficient or inappropriate to sterilize the material. *See Phillips*, 415 F3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that

the limitation is not present in the independent claim"). Accordingly, the Court interprets the term "irradiated" in claims 50 of the '934 Patent consistently with claim 23, that is, to mean "exposed to radiation." Such meaning includes, but is not limited to, "sterilization irradiation."

In addition, claims 23 and 50 of the '934 Patent, claims 7 and 19 of the '814 Patent, and claims 1, 12 and 24 of the '308 Patent all state that the claim requires the material to be irradiated "to create free radicals" or that the claim is for a method for "creating free radicals . . . by irradiating" the material. Since the express purpose of the irradiation process described by the claims is the production of free radicals, not sterilization, the claims themselves do not support defendants effort to limit the process to "sterilization irradiation." The Court finds that the meaning of the term "irradiation" is consistent throughout the '934, '814, and '308 Patents: "irradiate" is not limited to "sterilization irradiate."

b. '020 Patent, claims 1, 6, 7, 10, 11, 12

The term "irradiated" in claims 1, 6, 7, 10, 11, and 12 of the '020 Patent is not clearly defined by the context of the other claims of that Patent. Though, as defendants point out, the '020 Patent's specification contemplates the process of irradiating the polymer material solely in the context of sterilization, '020 Patent, 3:40-7:37, the Court does not conclude that the

specification is intended by the inventor to *define* "irradiation" only as "sterilization irradiation." Because the other, related patents used the term "irradiated" more broadly than "sterilization irradiation," the Court will give the term its ordinary, broader meaning in the '020 Patent as well. *See Inline Connection Corp. v. AOL Time Warner Inc.*, 302 F. Supp. 2d 307, 324 (D. Del. 2004) (construing term "tranceiver" uniformly, as having broad ordinary meaning, through entire patent family). In all of the claims at issue, the Court interprets "irradiated" to carry its ordinary meaning: "exposed to radiation."[7]

3. *Method of Segregation from Oxygen During Irradiation and Heating Steps*

Defendants argue that the patent claims require the irradiation and heating steps of the process to occur in an airtight package.[8] Howmedica argues that the patent

7. The Court rejects Defendants attempt to use the prosecution histories of the '049 and '748 Patents to limit the disputed claims to sterilization radiation for the reasons recited above. The '049 Patent contains distinct claim terms, and the '748 Patent communication does not amount to a clear limitation of "radiation" to "sterilization irradiation."

8. As mentioned, defendants construe the patents-in-suit to disclose only a process whereby the finished implant is enclosed in its final package, and is then the package is irradiated and heated. This is the process described in the preferred embodiment. Accordingly, defendants use the term "package" to refer to a packaging material which surrounds a finished implant.

claims allow these steps to occur in some other type of reduced-oxygen environment.

a. heated "out of contact with oxygen"

Seven of the claims at issue state that the material being processed is kept "out of contact with oxygen:"[9]

> *'934 Patent, claims 23, 50; '814 Patent, claim 7*: "said material irradiated . . . and then heated while out of contact with oxygen in a concentration greater than 1% volume by volume"
>
> *'814 Patent, claim 19*: "irradiating . . . and annealing said material while out of contact with oxygen in a concentration greater than 1% volume by volume"
>
> *'308 Patent, claim 1*: "irradiating . . . and heating the polyethylene material forming the implant . . . while said polyethylene material is prevented from contact with oxygen in a concentration greater than 1% volume by volume"

9. Five claims, which the Court will discuss later, state that the material is surrounded by a "layer of material" that prevents contact with oxygen when heated.

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> *'308 Patent, claim 12*: "creating free radicals in the polymer chain by irradiating the ultrahigh molecular weight polyethylene material [and] preventing oxygen from bonding with the said created free radicals by preventing them from coming into contact with oxygen in a concentration greater than 1% volume by volume . . . and heating the polymer . . . prior to exposing the free radicals to oxygen above the said concentration"
>
> *'308 Patent, claim 24*: "ultra high molecular weight polyethylene material . . . which has been irradiated . . . and then heated while out of contact with oxygen in a concentration greater than 1% volume by volume"

Howmedica argues that the Court should interpret "while out of contact with oxygen in a concentration greater than 1% volume by volume" as "without the UHMWPE [ultra-high molecular weight polyethylene] material contacting the surrounding atmosphere that contains oxygen in a concentration greater than 1% volume by volume." Defendants argue that "while out of contact with oxygen in a concentration greater than 1% volume by volume" means "in an airtight package with less than 1% oxygen by volume." Defendants refer to the process described in the summary of the invention and the preferred embodiment in the specification to narrow the scope of the invention. The Court rejects defendants' argument.

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Defendants point out that the specifications only describe a process whereby the implant is irradiated and heated after it is placed in a package from which the oxygen is expelled. Nevertheless, the Court does not find that the specification was intended to implicitly limit the meaning of "while out of contact with oxygen in a concentration greater than 1% volume by volume" to "in an airtight package." In the context of other claims in the patents, the claims at issue clearly intend a broader meaning for "out of contact with oxygen" than "in an airtight package," and so the Court will give the term the broader meaning.

i. '934 Patent, claims 23, 50

Related dependent claims do not support defendants' definition of the phrase "while out of contact with oxygen in a concentration greater than 1% volume by volume" in independent claim 23 of the '934 Patent. Dependent claim 33 is for "[t]he medical implant as set forth in claim 23 wherein an oxygen impermeable packaging material is the layer used to prevent the polyethylene material from contacting oxygen." '934 Patent, claim 33. The Court will not read a limitation expressly stated in the dependent claim (claim 33) into an independent claim that does not contain that limitation (claim 23). *See Phillips*, 415 F.3d at 1314-15. The limitation in dependent claim 33 implies that "while out of contact with oxygen in a concentration greater than 1% volume by volume" in claim 23 of the '934 Patent

is intended to contemplate methods of segregating the material from oxygen that do not involve "oxygen impermeable packaging materials."

Similarly, dependent claim 55 of the '934 Patent limits the device set forth in claim 50 to processes whereby an "oxygen impermeable packaging material" is used to prevent contact with oxygen. The Court finds that the irradiation and heating steps described in claims 23 and 50 of the '934 Patent are not limited to heating and irradiation "in an airtight package"—unlike the processes described by dependent claims 33 and 55, which are so limited.

ii. '308 Patent, claims 1, 12

Identical logic dictates that independent claims 1 and 12 of the '308 Patent are not limited to heating and irradiating the polyethylene "in an airtight package." Dependent claims 2 and 3 of the '308 Patent are for the method set forth in independent claim 1, but specify that the process takes place in an oxygen impermeable packaging material:

> 2. The method set forth in claim 1, wherein the contact with oxygen is prevented by sealing the polyethylene within an oxygen impermeable barrier.
>
> 3. The method as set forth in claim 2, wherein the oxygen impermeable barrier is a packaging material.

'308 Patent, claims 2, 3. Once again, the Court will not read the limits expressly stated in the dependent claims (*i.e.* claims 2 and 3) into the independent claim (*i.e.* claim 1). *See Phillips*, 415 F.3d at 1314-15. Dependent claims 13 and 14 of the '308 Patent similarly limit the process described in claim 12, and the express limits of the former claims should not be imported into the latter. Accordingly, the Court finds that claims 1 and 12 of the '308 Patent are not limited to a process whereby the polymer is heated and irradiated "in an airtight package."

iii. '308 Patent, claim 24

Claim 24 of the '308 Patent contains language which is very similar to that of claims 1 and 12 of that patent. In general, similar terms in different claims should be construed consistently. *See Phillips*, 415 F.3d at 1314 ("usage of a term in one claim can often illuminate the meaning of the same term in other claims"). The Court construes "heated while out of contact with oxygen" in claim 24 of the '308 Patent consistently with "heating . . . while . . . prevented from contact with oxygen" in claim 1 of the '308 Patent. In addition, the language of claim 24 of the '308 Patent is nearly identical to the language of claims 23 and 50 of the '934 Patent and claim 7 of the '814 Patent, which the Court has already found do not require segregation "in an airtight package." Claim 24 of the '308 Patent does not require segregation from oxygen "in an airtight package."

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iv. '814 Patent, claims 7, 19

Independent claim 19 of the '814 Patent does not require an "airtight package" to surround the material during the irradiation and heating steps. Unlike claim 19, dependent claim 20 of the '814 Patent refers to an "oxygen impermeable barrier around [the polyethylene material] prior to irradiating." Because a court should not read express limitations from dependent claims into independent claim's that lack that limitation, "while out of contact with oxygen" in claim 19 should not be limited to claim 20's "[surrounded by an] oxygen impermeable barrier." Accordingly, the Court will not limit the term "while out of contact with oxygen" in claim 19 to "in an airtight package," the even narrower construction that defendants urge for the claim.

The Court construes "while out of contact with oxygen" in claim 7 of the '814 Patent consistently with the term's use in claim 19. Neither claim requires that the heating step occur "in an airtight package."

b. "surrounded by a layer of material"

As the Court has noted, five of the claims at issue state that the polymer material is processed while surrounded by a layer of material that prevents contact with oxygen:

> *'934 Patent, claims 29, 52*: "material is surrounded by a layer of material whose

> function is to prevent said . . . material from contact with oxygen and said layer is heated"
>
> '*814 Patent, claim 12*: "device as set forth in claim 7 wherein a layer of material is provided to prevent said polyethylene material from coming into contact with oxygen"
>
> '*308 Patent, claim 10*: "polyethylene implant material is surrounded by a layer of material whose function is to prevent said polyethylene material from coming into contact with oxygen, said layer of material is heated"
>
> '*308 Patent, claim 21*: "polyethylene is surrounded by a layer of material whose function is to prevent said polyethylene material from said contact with oxygen, said layer of material is heated"

The ordinary meaning of these claim terms is narrower than the seven claims the Court examined earlier, which merely involved an unspecified method of isolation from oxygen. However, the Court's analysis of these claims is similar to the analysis it employed earlier.

i. '934 Patent, claims 29, 52

The Court finds that claims 29 and 52 of the '934 Patent, which specify that the polymer is segregated

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from oxygen by a layer of material, are not limited to processes that segregate the polymer from oxygen by a packaging material. This is because the doctrine of claim differentiation suggests that when two distinct claims depend from one independent claim, they should not be read to place the same limitations on that independent claim. Otherwise the dependent claims would render one another superfluous.

Claims 29 and 33 both depend from independent claim 23 of the '934 Patent, but limit claim 23 differently. Dependent claim 29 limits claim 23 of the '934 Patent to processes whereby the polymer "is surrounded by a layer of material" to segregate from oxygen. In contrast, dependent claim 33 of the '934 Patent limits dependent claim 23 to processes whereby an "oxygen impermeable packaging material is the layer used to prevent the polyethylene material from contacting oxygen." The doctrine of claim differentiation strongly suggests that claim 29 is distinct from, and broader than, claim 33.

Similarly, claims 55 and 52 both depend from independent claim 50 of the '934 Patent. Dependent claim 55 of the '934 Patent limits independent claim 50 to processes wherein an "oxygen impermeable packaging material is used to prevent the olefinic material from contacting oxygen," while dependent claim 52 of the '934 Patent only limits claim 50 to processes whereby the polymer is segregated from oxygen by "a layer of material." This implies that claim 52 is broader in scope than claim 55.

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The Court therefore finds that claims 29 and 52 of the '934 Patent, unlike claims 33 and 55, are not limited to processes whereby the polymer is isolated from oxygen by an airtight package.

ii. '308 Patent, claims 10, 21

Applying identical reasoning, the Court finds claims 10 and 21 of the '308 Patent, which specify that the polymer is segregated from oxygen by a "layer of material," are not limited to using an airtight package to prevent the polymer from contacting oxygen.

Claims 3 and 10 both depend from independent claim 1 of the 308 Patent. Dependent claim 3 of the '308 Patent expressly limits independent claims 1 of that patent to processes wherein the method for preventing the polyethylene material's contact with oxygen is "a packaging material." In contrast, dependent claim 10 limits claim 1 of that patent to processes whereby "a layer of material" prevents the polyethylene material's contact with oxygen. The doctrine of claim differentiation suggests that the language of claim 10 is intended to convey a broader scope for that claim than the precise and narrow language of claim 3 of the '308 Patent.

Dependent claims 21 and 14 both depend from independent claim 12 of the '308 Patent. Dependent claim 14 of the '308 patent expressly limits independent

claim 12 of the '308 Patent to processes whereby the method for preventing the polyethylene material's contact with oxygen is "a packaging material." This implies that claim 21, which specifies that a "layer of material" segregates the polymer from oxygen, is intended to be broader in scope than the narrowly defined claim 14 of the '308 Patent.

Neither claim 10 nor claim 21 of the '308 Patent require the polymer be heated "in an airtight package." In other words, the material used to segregate the polymer from oxygen does not have to be a packaging material.

iii. '814 Patent, claim 12

The meaning of "layer of material" in claim 12 of the '814 Patent is not so easily construed in the context of that patent's other, related claims. Even so, the Court will not interpret the term to require the polyethylene material be isolated from oxygen by an airtight package. First, the language of claim 20, referring to an "oxygen impermeable barrier around said material," suggests that "layer of material" is distinct from and broader than "in an airtight package." Second, because the related '934 and '308 Patents used the term "layer of material" more broadly than "an airtight package," the Court will not narrow the term merely on the basis of a specification that does not clearly limit the invention to the embodiment. *See Inline Connection Corp. v. AOL Time*

Warner Inc., 302 F. Supp. 2d 307, 324 (D. Del. 2004). The Court interprets "layer of material" to mean exactly what it says and no more. The phrase does not restrict claim 12 to sterilization and heating "an airtight package."

4. *Temperature Range of the Heating Step of Processing*

Defendants argue that the claims at issue require that the heating stage of the process must occur at a temperature between 25°C and a specified upper limit. Howmedica asserts that the claims do not specify an upper temperature limit for the heating stage.

> '934 Patent, claims 23, 50; '814 Patent, claim 7; '308 Patent, claim 24: "said material . . . heated . . . at a temperature . . . greater than 25°C"
>
> *'814 Patent, claim 19*: "annealing said material . . . at a temperature greater than 25°C"
>
> *'308 Patent, claims 1, 12*: "heating the [polyethylene material/polymer]"
>
> *'308 Patent, claims 5, 16*: "method as set forth in claim [1/12], wherein the temperature is greater than 25°C"

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> *'020 Patent, claims 10, 11, 12*: "medical implant comprising an ultra-high molecular weight polyethylene . . . annealed at a temperature of greater than 25°C"

Howmedica proposes that the phrase "at a temperature [. . .] greater than 25°C" requires no interpretation. Defendants argue that the Court should interpret this phrase as "at a temperature of greater than 25°C but less than 140°C." Defendants refer to the summary of the invention and the preferred embodiment in the specification to narrow the scope of the claim. They observe that the process described in the specification does not include situations wherein the material is heated at a temperature greater than its melting point. The Court rejects defendants' argument.

a. "heating" / "heating at a . . . temperature greater than 25°C"

i. '934 Patent, claims 23, 50

Related dependent claims do not support defendants' proposed limitation of the ordinary meaning of the terms "heating" and heating "at a temperature [. . .] greater than 25°C" in independent claims 23 and 50 of the '934 Patent. Dependant claims 30 and 53 of the '934 Patent are for "[t]he medical implant . . . wherein said heating has an upper temperature limit of the melting point of the . . . material." '934 Patent, claims

30, 53.[10] Dependent claims 32 and 54 are for "[t]he medical implant . . . wherein said heating has an upper limit not exceeding the distortion temperature of the . . . material." '934 Patent, claims 32, 54. In contrast, independent claims 23 and 50 of the '934 Patent do not specify any upper temperature limit on the heating process. The express upper temperature limits in the four dependent claims imply that heating "at a temperature . . . greater than 25°C," without any express upper limits, includes processes whereby the material is heated above its melting or distortion point, approximately 140°C. *See Phillips*, 415 F.3d at 1314-15 (express limitations in dependent claims should not be read into independent claims). The Court finds that the heating processes described by claims 23 and 50 of the '934 Patent are not limited to an upper temperature of 140°C.

ii. '814 Patent, claim 7

Limitations on a related dependant claim also imply that "heated . . . at a temperature . . . greater than 25 C" in claim 7 of the 814 Patent does not disclose an upper limit on the heating of the polymer. Dependent claim 10 of the '814 Patent is for "[t]he device . . . wherein the

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10. The description of the preferred embodiments indicates that the melting point or distortion temperature of ultra-high molecular weight polyethylene is "about 140°C." *See, e.g.*, '934 Patent, 5:55-58; 6:66-7:02.

polyethylene material is heated to a temperature between 25°C and the melting point of said polymer," which implies that independent claim 7 of the '814 Patent is not so limited because it specifies no upper temperature limitation. *See Phillips*, 415 F.3d at 1314-15. The Court finds that claim 7 of the '814 Patent does not place an upper temperature limit of 140EC on the heating process.

iii. '308 Patent, claims 1, 5, 12, 16, 24

Likewise, limitations on a related dependant claim imply that the disputed claims of the 308 Patent do not disclose an upper limit on the heating of the polymer. Dependent claims 9 and 20 of the '308 Patent are for "the method . . . wherein the polyethylene material is heated to a temperature . . . between 25°C and the melting point of said polymer." '308 Patent, claims 9 and 20. The limitations established in all of these dependent claims lead the Court to find that independent claims 1 and 12 of the '308 Patent, which only specify "heating the polyethylene material," may include processes whereby the material is heated above 140°C. *See Phillips*, 415 F.3d at 1314-15. Claims 5 and 16 of the '308 Patent limit the invention described in claims 1 and 12 to processes "wherein the temperature is greater than 25°C," but do not specify any upper limit. '308 Patent, claims 5, 16. Applying the doctrine of claim differentiation, the Court finds that claims 5 and 16 include processes that involve heating the polymer to a temperature greater than 140°C.

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Claim 24 of the '308 Patent specifies that the material is heated at a "temperature of greater than 25°C." '308 Patent, claim 24. Reading the language of claim 24 consistently with claims 5 and 16, the Court finds that claim 24 of the '308 Patent is not limited to heating at a temperature of less than 140°C.

b. "annealed at a temperature of greater than 25°C"

i. '020 Patent, claims 10, 11, 12

The language of the '020 Patent claims is less clear because the context does not clarify the definition of the claims at issue. Also, the '020 Patent claims differ from those of the other patents because they use the word "anneal" rather than "heat." The Court will not base its interpretation of these claims on its construction of the '934, '814, and '308 Patents, and will look to the specification to define the term "anneal" in the '020 Patent claims. The '020 Patent specification only describes an annealing process which takes place at a temperature between 25°C and 140°C. This confirms the Court's understanding of the plain language definition of the term "anneal," which is method of changing a material's physical properties by heating a material to a point below its melting point and then cooling that material. The Court will interpret "annealed at a temperature of greater than 25°C" in claims 10, 11, and 12 of the '020 Patent to mean exactly that: "annealed at

a temperature of greater than 25°C" and less than the melting point of that material – approximately 140°C.

ii. '814 Patent, claim 19

Claim 19 of the '814 Patent similarly states that the method of treatment consists of "annealing said material . . . at a temperature greater than 25°C," unlike the other disputed claims of that patent, which disclose the "heating" of the material. Looking towards the ordinary meaning and the specification, the Court finds that claim 19 of the '814 Patent describes a process of heating the material to a temperature between 25°C and 140°C.

c. Prosecution History

The Court rejects Defendants' resort to the prosecution histories of the '934, '471, and '485 Patents because the prosecution history does not demonstrate that Howmedica limited the upper temperature of the heating stage in response to the examiner's objections. In amending its '934 Patent, Howmedica did not add an upper temperature limit; Howmedica lowered the lower temperature limit. In his objection to the '471 and '934 Patent claims, the examiner was objecting to the claims' highly imprecise temperature and duration language, not to the lack of an upper temperature limit of 140°C.

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5. *Relationship of Duration of Heating Step to Its Temperature*

> *'934 Patent, claims 23, 50; '814 Patent, claims 7, 19; '308 Patent, claim 1, 12, 24*: heating material at a temperature and for a time at least equivalent to heating "at 50°C for 144 hours as defined by . . . Arrhennius' [sic] equation (14)."[11]

The 9 claims at issue here require the heating of the material at a temperature and for a period at least equivalent to heating the material "at 50°C for 144 hours as defined by . . . Arrhennius' equation (14)." Defendants argue that this phrase needs no construction. But, they add, should the Court decide to interpret the phrase, it means "as defined by equation 14 from the patent specification." In its original claim construction brief, Howmedica argued that Arrhenius' equation, in the case of ultra-high molecular weight polyethylene, should be construed as dictating that for every 10°C increase of the heating temperature the required duration of

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11. Arrhenius' equation, named after the Swedish chemist Svante August Arrhenius, which will be discussed in greater detail below, expresses a mathematical relationship between the reaction temperature and the rate at which a reaction occurs. *See* '934 Patent, 6:55-6:65.

heating is halved.[12] In its supplementary filing of November 2006, Howmedica does not offer any construction of this term, implying that there is no need for construction.[13] The Court agrees that construction of this phrase is not required at this time, because it clearly refers to Arrhenius' equation as it is defined by equation 14 in the '934, '814, and '308 Patent specifications. *See, e.g.*, '934 Patent, 6:58.

6. *Construction of "Oxidation Index"*

Howmedica argues that the Court should construe this term to mean "a relative measurement of the amount of oxidized material present in the UHMWPE." Defendants propose that oxidation index should be read to mean "the area of the IR absorbtion peaks in the

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12. Claim 23 calls for the ultra-high molecular weight polyethylene to be heated for 144 hours at 50°C, or the equivalent thereof according to Arrhenius' equation. Under Howmedica's simplified construction, as example, the polyethylene may be heated for 72 hours at 60°C, or for 36 hours at 70°C.

13. In its subsequent opposition to Zimmer's motion for summary judgment, Howmedica relies on expert declarations to oppose Zimmer's position that this term is invalid for indefiniteness. One of these expert declarations expressly contradicts Howmedica's initial position here, i.e. that the Arrhenius equation is construable as a simple relationship halving the duration of heating for every 10°C increase. (Howmedica Opp'n to Summary Judgment, Risen Decl. at 7.)

frequency range of between 1660 and 1800/cm divided by the area of the 1463/cm peak."

> '020 Patent, claim 3: "the polyethylene has an FTIR . . . oxidation index which does not increase with oven aging in air . . ."
>
> '020 Patent, claims 6, 10: "polyethylene having . . . an oxidation index which does not increase during oven aging in air"
>
> '020 Patent, claim 7: "polyethylene having . . . a non-increasing FTIR oxidation index during oven aging in air"
>
> '020 Patent, claim 11: "polyethylene . . . irradiated and annealed . . . for a sufficient time to have an non-inreasing FTIR oxidation index of .01 during oven aging in air"
>
> '020 Patent, claim 12: "polyethylene . . . irradiated and annealed . . . for a sufficient time to have an non-inreasing FTIR oxidation index of .01 or less during oven aging in air"

The meaning of this term is impossible to derive from the language of the claim itself, nor is the ordinary meaning of this term apparent to the Court. Howmedica's sole foundation for its interpretation is Dr. Stephen Li's conclusory assertion of what a person of

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the ordinary skill in the art would understand "oxidation index" to mean.

In contrast, to support their construction, defendants point to the sole occasion in which the term "oxidation index" appears in the '020 Patent specification. The term appears in the context of an involved description of how the oxidation index for a particular set of materials was obtained:

> Two sets of 1-mm-thick UHMWPE sheets prepared by Methods A through D above were oven aged in air at 80°C for 11 and 23 days respectively. After these sheets were cooled in room temperature, a thin film specimen of about 100 microns in thickness was cut from each of the 1-mm-thick aged UHMWPE sheets and placed in an IR window for a standard FTIR (A Nicolet 710 FTIR system was used) transmission run. A total of 32 spectra (scans) was collected and averaged. To determine the extent of oxidation, the IR absorption peaks in the frequency range of between 1660 and 1800 cm^{-1}, corresponding to carbonyl (C—O) functional groups, were integrated for the peak area. The peak area is proportional to the amount of oxidized UHMWPE in the specimen. To correct for difference in specimen thickness, the integrated peak area was then normalized to

> the specimen thickness, by dividing by the area of the 1463 cm^{-1} (methyl) peak which is proportional to the specimen thickness. *The obtained ratio was defined as oxidation index.*

'020 Patent 7:63-8:13 (emphasis added). This portion of the specification expressly defines the term "oxidation index" to mean a ratio which is derived from the spectroscopic measurements described by the specification. When the specification gives a special definition to a term, that definition trumps the ordinary meaning of that term. *See Phillips*, 415 F.3d at 1316; *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Markman*, 52 F.3d at 979-80. Accordingly, the Court adopts the definition of "oxidation index" expressed by the specification.[14]

III. DEFENDANTS' MOTION TO STRIKE TESTIMONY OF DR. LI

In support of its claim construction memoranda, Howmedica filed two declarations by Dr. Stephen Li. Howmedica characterizes these two documents as

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14. To the extent that defendants' proposed definition accurately conveys the process for obtaining an oxidation index for UHMWPE material, the Court adopts that definition. If the parties further contest the construction of this term, additional briefing and/or arguments may be required.

declarations by a person of the ordinary skill in the art. Defendants characterize Dr. Li's declarations as expert testimony subject to the admissibility standards of Federal Rule of Evidence 702. Defendants assert that under Rule 702's standards the Court should strike Dr. Li's declarations as inadmissible.

The Court is mindful of the Federal Circuit direction that district courts look first towards intrinsic evidence when they construe patent claims. *Markman*, 52 F.3d at 979. As this Court has noted in a previous patent decision, it is wary of the reliability of expert evidence produced solely for the purposes of claim construction. *Ricoh Co., Ltd. v. Katun Corp.*, 380 F.Supp.2d 418, 423 (D.N.J. 2005); *Vitronics*, 90 F.3d at 1584. This is particularly so when the expert testimony is largely conclusory in its assertions – as Dr. Li's declarations are. *Phillips*, 415 F.3d at 1318.[15]

The Court relied solely on the intrinsic evidence in the patent record to construe the claims at issue here. Since the Court did not ultimately rely on Dr. Li's

15. Troublingly, Dr. Li's declarations often state how a person of the ordinary skill in the art would interpret a term, without furnishing (1) sufficient rationale for the Court to evaluate that construction and (2) any indication of how Dr. Li defines such a person. Implicitly, Dr. Li relies upon his own understanding of a term to arrive at the construction a person of the ordinary skill in the art would endorse.

declarations for its construction, it will not unnecessarily determine whether they are admissible.

IV. DEFENDANTS' MOTION TO STRIKE HOWMEDICA'S SUPPLEMENTAL FILING OF NOVEMBER 2006

Defendants also move to strike Howmedica's supplemental filing of November 13, 2006. First, they argue that Howmedica represented to the Court, during an October 23, 2006 conference call, that only ten claims required construction. Second, they argue that Howmedica used its filing, which the Court had requested to clarify the parties' claim construction dispute, to advance novel interpretations of various claims. Defendants cite no controlling legal authority for their motion. The Court sees no merit in either of defendants' arguments because it disagrees with defendants' factual assertions.

Howmedica represented that it would ask the Court to construe approximately ten independent claims. Its supplemental filing asks the Court to construe twelve independent claims. Howmedica's supplementary filing is largely consistent with its earlier filings. Where variations exists, they are minor and ultimately immaterial to the Court's construction.

The Court will not strike the Howmedica's supplemental claim construction filing.

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V. CONCLUSION

It is on this 23rd day of April, 2007:

ORDERED that parties' motions for claim construction are decided as set forth by this opinion;

ORDERED that defendants' motion to strike the declarations of Dr. Stephen Li is DENIED; and

ORDERED that defendants' motion to strike Howmedica's supplemental filing of November 2006 is DENIED.

/s/
William H. Walls
United States Senior District Judge

APPENDIX I — RELEVANT STATUTE

35 § 112

§ 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation

of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

(July 19, 1952, c. 950, 66 Stat. 798; July 24, 1965, Pub.L. 89-83, § 9, 79 Stat. 261; Nov. 14, 1975, Pub.L. 94-131, § 7, 89 Stat. 691.)

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Supreme Court, U.S.
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No. 10-1161

Supreme Court of the United States

HOWMEDICA OSTEONICS CORP.,
Petitioner,

v.

ZIMMER, INC. AND CENTERPULSE ORTHOPEDICS, INC. (FORMERLY KNOWN AS SULZER ORTHOPEDICS, INC.) AND SMITH & NEPHEW, INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENTS' JOINT OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents Zimmer, Inc. and Centerpulse Orthopedics, Inc. state that Centerpulse Orthopedics, Inc. changed its name to Zimmer Austin, Inc. and was merged into Zimmer, Inc. Zimmer, Inc. is wholly-owned directly and indirectly by Zimmer Holdings, Inc. There is no parent corporation or any publicly-held corporation that owns 10% or more of Zimmer Holdings, Inc.'s stock. No other publicly-held company owns 10% or more of Zimmer, Inc.'s or Centerpulse Orthopedics, Inc.'s stock.

Pursuant to Supreme Court Rule 29.6, Respondent Smith & Nephew, Inc. states that Smith & Nephew, Inc. is a wholly owned, indirect subsidiary of Smith & Nephew plc. Smith & Nephew plc is a public entity incorporated under the laws of England and Wales. No publicly held corporation owns more than 10% or more of the securities of Smith & Nephew plc.

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ARGUMENT

Petitioner did not timely raise the Questions Presented, and as a result, the lower courts did not issue opinions on either of the questions now presented to this Court. Moreover, Petitioner challenges the lower courts' routine application of the well-entrenched standard for determining indefiniteness at the summary judgment stage. Petitioner's request for factbound error correction, where there is no error, should be denied.

I. PETITIONER DID NOT RAISE THE QUESTIONS PRESENTED IN THE LOWER COURTS.

Petitioner did not raise the first question presented—relating to a patentee's Seventh Amendment right to a jury trial on the issue of indefiniteness—in either of the courts below. Consequently, none of the parties briefed this issue nor did the Federal Circuit or District Court address it in their opinions.

Petitioner did not raise the second question presented—relating to the Federal Circuit's alleged treatment of indefiniteness as a pure question of law—until its petition for *en banc* review at the Federal Circuit. The Federal Circuit denied Petitioner's *en banc* request without opinion. (Pet. App. at 1a-2a).[1] Consequently, Respondents did not have a chance to brief this issue at the District

[1] Pet. App. refers to Petitioner's Appendix.

Court, and neither the Federal Circuit nor District Court addressed it in their opinions.

Indeed, because the Federal Circuit affirmed the District Court's opinion per curiam under Federal Circuit Rule 36, there is no appellate opinion at all. (Pet. App. at 3a-4a). "Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them." *Penn. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212-13 (1998) (citations and quotation marks omitted); *see also Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005) ("[W]e are a court of review, not of first view."); *City of Springfield v. Kibbe*, 480 U.S. 257, 258 (1987) ("We ordinarily will not decide questions not raised or litigated in the lower courts."). Petitioner has offered no reason for this Court to depart from its ordinary practice here. Accordingly, the Petition should be dismissed for this reason alone.

II. PETITIONER'S ARGUMENTS ARE BASED ON FALSE LEGAL PREMISES.

Petitioner relies on an incorrect recitation of the law of indefiniteness. First, the legal standard for indefiniteness was not altered by this Court's decision in *Markman v. Westview*, 517 U.S. 370, 388-390 (1996). Second, the Federal Circuit never precluded the issue of indefiniteness from ever being subject to underlying factual determinations. Therefore, the Petition is based on entirely false legal premises.

A. THE LEGAL STANDARD FOR JUDGING INDEFINITENESS HAS NOT CHANGED SINCE THIS COURT'S *MARKMAN* DECISION.

The Federal Circuit did not change the legal standard for judging indefiniteness subsequent to this Court's decision in *Markman v. Westview Instruments*, Inc., 517 U.S. 370, 388-390 (1996).

Prior to *Markman*, the Federal Circuit held the question of indefiniteness is a matter of law subject to *de novo* review. *See, e.g., N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993), *citing Stiftung v. Renishaw plc*, 945 F.2d 1173, 1181 (Fed. Cir. 1991). The test for indefiniteness was "whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification." *Id., citing Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986); *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

Contrary to Petitioner's assertion, the Federal Circuit has not since changed its view of the law of indefiniteness. It continues to be a question of law that is subject to *de novo* review. *Honeywell Intern., Inc. v. U.S.*, 609 F.3d 1292, 1301 (Fed. Cir. 2010); *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1366 (Fed. Cir. 2010). The test remains whether those skilled in the art would understand the scope of the claim when read in light of the specification. *Amgen Inc. v. F. Hoffman-LA Roche Ltd.*, 580 F.3d 1340, 1371 (Fed. Cir. 2009), *citing Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

Therefore, the Federal Circuit did not "inconsistently extend" this Court's *Markman* decision to indefiniteness as Petitioner suggests. (Pet. Brief at 15). Indeed, the Federal Circuit's standard for judging indefiniteness has remained constant since at least the passage of the Patent Act of 1952.

B. CONTRARY TO THE PETITIONER'S ARGUMENT, INDEFINITENESS CAN BE SUBJECT TO UNDERLYING FACTUAL DETERMINATIONS.

Petitioner wrongly claims that Federal Circuit law developed since *Markman* holds that a determination of indefiniteness on summary judgment can *never* be subject to underlying factual issues. The Federal Circuit's precedent expressly contradicts this claim.

As recently as last year, the Federal Circuit made clear that "[d]efiniteness, under 35 U.S.C. §112, paragraph 2, and enablement, under paragraph 1, are *both questions of law with underlying factual determinations*." *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1299 (Fed. Cir. 2010) (emphasis added). The Federal Circuit has also found that certain circumstances may make determining definiteness "amenable to resolution by the jury where the issues are factual in nature." *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003). As a result, the Federal Circuit properly reviews the ultimate question of indefiniteness *de novo*, while reviewing factual findings for clear error. *Tech. Licensing*

Corp. v. Videotek, Inc., 545 F.3d 1316, 1338 (Fed. Cir. 2008) (citations omitted).

The lower courts have consistently applied this standard, allowing juries to address underlying factual questions on the issue of indefiniteness when appropriate. *Sys. Mgmt. Arts Inc. v. Avesta Techns., Inc.*, 137 F. Supp. 2d 382, 399-400 (S.D.N.Y 2001) (finding "numerous district courts have treated the issue of indefiniteness under §112 ¶2 as an inquiry that is a question of law with underlying issues of fact"). As one court has stated:

> In light of the above persuasive authority, the Court concludes that the law on indefiniteness is not as rigid as NOVA contends. Although it may generally behoove the Court to address indefiniteness as a legal matter in the context of claim construction, there may arise cases where genuine issues of fact simply preclude such a treatment. In these circumstances, the question of indefiniteness must be addressed by the trier of fact.

Dow Chem. Co. v. NOVA Chems. Corp. (Canada), 629 F. Supp. 2d 397, 404 (D.Del. 2009) (finding "numerous district courts—both before and after *System Mgmt.*—appear to have followed this or similar reasoning") (citations omitted).

Petitioner ignores these more recent decisions from the Federal Circuit and various District Courts. Instead, Petitioner argues that in *Exxon Research & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1376 (Fed. Cir. 2001), the Federal Circuit held that resolving the

issue of indefiniteness can never be subject to underlying factual determinations. (Pet. Br. at p. 16, 26). But the *Exxon* holding is not so broad; in *Exxon* the Federal Circuit simply reiterated that indefiniteness is a question of law "that is drawn from the court's performance of its duty as the construer of patent claims." *Id.* at 1376. Construing patent claims inherently requires a court to analyze a patent's intrinsic and extrinsic evidence.[2] *Id.* *Exxon* clarifies that performing the claim construction analysis does not necessarily result in a court improperly deciding underlying factual issues that prevent summary judgment. *Id.* As one lower court put it:

> Of course, if the issue of indefiniteness can be resolved based on the intrinsic evidence alone, then the question of possible disputes of underlying fact based on conflicting expert evidence will not arise, since extrinsic evidence is not properly considered in that situation. *See Vitronics*, 90 F.3d at 1584. Moreover, the fact that extrinsic evidence may be considered does not necessarily mean there is a genuine dispute of fact. This question must be evaluated under the ordinary standards applicable to a summary judgment motion, and bearing

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[2] Intrinsic evidence consists of the information in the patent itself (*i.e.*, the claims and specification) and the patent's prosecution history. Extrinsic evidence consists of all evidence that is external to the patent and prosecution history. Intrinsic evidence is considered more important and reliable in construing a patent's claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-1319 (Fed. Cir. 2005).

> in mind the burden of proof on the party alleging invalidity.

Sys. Mgmt. Arts Inc. v. Avesta Techs., Inc., 137 F. Supp. 2d 382, 400 (S.D.N.Y 2001).

This standard comports with this Court's recent precedent relating to a patent's invalidity for obviousness under 35 U.S.C. §103:

> In considering summary judgment on that question [obviousness] the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. [citation omitted]. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 426-427 (2007). Therefore, this Court has already issued guidance on the proper role of the court when judging patent validity issues as a matter of law.

Petitioner's argument that *Exxon* prevents indefiniteness from ever involving an underlying factual issue is incorrect. Cases both before and

after *Exxon* demonstrate that the Federal Circuit has never pronounced, nor have the lower courts ever followed, such a rule.

III. BECAUSE THE LOWER COURTS APPLIED THE PROPER LEGAL STANDARD, THE APPLICATION OF THAT STANDARD TO THE FACTS OF THIS CASE IS NOT SUFFICIENTLY IMPORTANT TO GRANT THE PETITION.

As shown above, neither *Markman* nor *Exxon* (nor any other case) changed the law of indefiniteness as Petitioner claims. And Petitioner does not contend that the lower courts used the wrong legal standard. Therefore, this case presents neither a historical conflict in the law of indefiniteness nor a conflict between the lower courts in how to apply the law of indefiniteness.

To the contrary, it is clear that Petitioner's real issue is the application of the law of indefiniteness and summary judgment principles to the facts of this case, which does not justify this Court's review. "A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." *Sup. Ct. R. 10*; *see also United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts."). The lower courts' application of settled precedent to the specific facts of this case simply does not warrant this Court's review.

Regardless, there was no error in the lower courts' judgments. Petitioner's principal contention

is that summary judgment should not have been granted because it provided expert testimony. (Pet. Br. at 5). But applying basic summary judgment principles to the question of indefiniteness, the District Court appropriately found the expert testimony insufficient to create a genuine issue of fact because it was:

- ***conclusory***, (Pet. App. at 46a-48a, 13a-14a; 95a, fn. 15);
    - "Conclusory expert assertions cannot raise triable issues of material fact on summary judgment." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1001 (Fed. Cir. 2008), *citing Dynacore Holdings Corp. v. U.S. Phillips Corp.*, 363 F.3d 1263, 1278 (Fed. Cir. 2004); *see also, Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000) (finding an expert's unsupported conclusions insufficient to raise a genuine issue of material fact.);
- ***contrary to the patent specification (i.e., the intrinsic evidence)***, (Pet. App. at 19a, 47a-48a); and
    - "As this court has repeatedly cautioned, extrinsic evidence cannot be used to vary the plain language of the patent document." *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1302 (Fed. Cir. 2005); *see also,*

Phillips v. AWH Corp., 415 F.3d. 1303, 1318 (Fed. Cir. 2005) ("Similarly, a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, the written record of the patent.'");

- ***contrary to earlier positions taken by those same experts before the discovery of invalidating prior art***, (Pet. App. at 45a, fn. 4 and 47a, fn. 5; 91a, fn. 13).
    - "[A] party may not create a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict." *Jiminez v. All Am. Rathskeller, Inc.*, 503 F.3d 247, 251-252 (3d Cir. 2007) (noting every federal court of appeals has adopted some form of the sham affidavit doctrine) (citations omitted); *see also, Sinskey v. Pharmacia Opthoalmics, Inc.*, 982 F.2d 494, 498 (Fed. Cir. 1992) ("A party cannot create an issue of fact by supplying an affidavit contradicting his prior deposition testimony, without explaining the contradiction or attempting to resolve the disparity.") (citations omitted),

> *abrograted in part on other grounds, Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998).

Therefore, the District Court was on solid legal ground in finding Petitioner's expert's declarations did not create a genuine issue of material fact that would preclude summary judgment. To find otherwise would make "summary judgment [ ] disappear from patent litigation." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1051 (Fed. Cir. 2001).

IV. CONCLUSION

Petitioner did not adequately raise below either of the questions it now presents this Court. As a result, neither the Federal Circuit nor the District Court issued an opinion on either question. Moreover, the case law makes clear that the law of indefiniteness has not changed over the past 50 years. Petitioner overstates the effect the *Markman* and *Exxon* decisions have had on the issue of indefiniteness in hopes of creating a legal issue worthy of this Court's review. This Court should deny Petitioner's request to review an issue that simply does not exist and that was not raised below.

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IN THE

Supreme Court of the United States

HOWMEDICA OSTEONICS CORP.,

Petitioner,

v.

ZIMMER, INC. AND CENTERPULSE ORTHOPEDICS, INC. (FORMERLY KNOWN AS SULZER ORTHOPEDICS, INC.), AND SMITH & NEPHEW, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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RULE 29.6 STATEMENT

Petitioner states that it previously submitted a Rule 14(B) and 29.6 Statement in its Petition For A Writ of Certiorari. Petitioner has no amendments to that Statement.

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ARGUMENT

I. THIS COURT MAY CONSIDER "PURELY LEGAL ISSUES" NOT RAISED WITH THE LOWER COURTS

Petitioner's request for *certiorari* raises two related questions of exceptional importance to patent law jurisprudence—(1) whether the U.S. Court of Appeals for the Federal Circuit has improperly eroded or eliminated a patent-holder's Seventh Amendment right to a trial by jury by making the invalidity for indefiniteness of patent claims (35 U.S.C. § 112, ¶ 2) a pure question of law for the court, and (2) whether the Federal Circuit improperly treats invalidity for indefiniteness as a pure question of law, particularly where the issue is whether a claim limitation can be calculated or measured. (*See* Petition at i.)

As Petitioner explains, invalidity for indefiniteness should properly be a jury issue because, unlike claim construction, it involves complex factual issues regarding how a person of ordinary skill in the art understands the patent claims and specification. (*See id.* at 18-24.) That is particularly true in cases such as this, where the indefiniteness issue does not revolve around the *meaning* of a patent claim term, but instead whether a claimed property can be *measured* or *calculated* by a person of ordinary skill in the art. (*See id.*) Here, Petitioner submitted testimony from two such experts, which was disregarded by the District Court in favor of Respondents' attorney argument. The complex factual disputes in this case, however, and the disputes raised by Petitioner's expert testimony, should have precluded summary

judgment, and should have triggered Petitioner's right to a jury trial.

Petitioner concedes that it did not expressly raise these legal arguments with the District Court[1]—indeed, it would have been entirely futile to ask the District Court to rule contrary to Federal Circuit precedent. Accordingly, Petitioner disputed the Federal Circuit's standard for indefiniteness at its first opportunity—in its petition for rehearing *en banc* to the Federal Circuit.[2] (*See* Petition at 11.) Respondents' argument that by doing so, Petitioner has thus waived its arguments before this Court is erroneous.

It is well recognized that an appeals court may consider arguments not raised with the lower courts "to address plain errors or defects affecting substantial rights, especially where, as here, the argument has been fully briefed and involves a purely legal issue." *U.S. v. Wimbley*, 553 F.3d 455, 460 (6th Cir. 2009) (citations omitted, emphasis added). *See also Bellotti v. Baird*, 428 U.S. 132, 143-44 n.10 (1976) (purely legal issue may be raised for the first time on appeal); *Singleton v. Wulff*, 428 U.S. 106, 121 (1976) ("The matter of what questions may be

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1. Petitioner did raise with the District Court the much related issues of Respondents' high and unsupported burden of proof on indefiniteness and the impropriety of granting summary judgment in view of underlying factual issues.

2. Respondents argue that the question of whether indefiniteness is properly a pure question of law was never "considered" by the Federal Circuit because it issued its decision *per curiam*. The Federal Circuit, however, did necessarily consider the issue, given that it comprised an entire section of Petitioner's Federal Circuit *en banc* brief.

taken and resolved for the first time on appeal is one left primarily to the courts of appeals, to be exercised on the facts of individual cases. We announce no general rule.")

Indeed, purely legal issues such as those raised here are frequently and properly considered for the first time on appeal, given that it is often impractical to ask a district court to rule on a matter of binding precedent or constitutionality. *U.S. v. Ballek*, 170 F.3d 871, 873 (9th Cir. 1999) ("Ballek raises his Thirteenth Amendment argument for the first time on appeal. Because this is a purely legal question, we exercise our discretion to overlook Ballek's waiver of the issue."); *White v. Department of the Army*, 232 U.S. App. D.C. 34, 720 F.2d 209, 211 (D.C. Cir. 1983) (considering statutory interpretation not raised below is "particularly appropriate where, as here, the question is a purely legal one, the resolution of which would not be aided by any further factual development"); *Federal Election Comm'n v. Lance*, 635 F.2d 1132, 1136 (5th Cir. 1981) (en banc) (constitutional argument could be raised for the first time on appeal).

Here, Petitioner's questions presented involve pure issues of law. Moreover, the facts pertinent to these issues were fully developed below. Accordingly, the Supreme Court should exercise its discretion and consider the arguments raised in the petition for *certiorari*.

II. RESPONDENTS MISSTATE THE FEDERAL CIRCUIT'S PRECEDENT—INDEFINITENESS IS IMPROPERLY TREATED AS A PURE ISSUE OF LAW UNDER FEDERAL CIRCUIT LAW

In its cert petition, Petitioner explained in detail that (1) the Federal Circuit has unequivocally held that invalidity for indefiniteness (35 U.S.C. § 112, ¶ 2) is a pure question of law for the Court; (2) such a holding is unsupported by this Court's prior precedent and is inconsistent with other Federal Circuit law; and (3) the District Court in this case expressly and incorrectly treated the indefiniteness issue as a pure question of law, resulting in an erroneous judgment. (*See* Petition at 10, 12-15.)

In response, Respondents ignore the central issue raised in Petitioner's petition, i.e., whether invalidity for indefiniteness is properly treated as a pure question of law for the Court, or a question of law with underlying factual disputes. Indeed, Respondents apparently concede that indefiniteness should be treated as a question of law with underlying factual disputes. Respondents, however, go one step further and argue that the Federal Circuit already treats it as such. Respondents' argument in this regard is incorrect.

A. The Federal Circuit Incorrectly Changed Its Treatment of Indefiniteness After The Supreme Court's *Markman* Decision

The Federal Circuit significantly, and erroneously, changed its jurisprudence regarding indefiniteness in view of the Supreme Court's 1996 decision in *Markman v.*

Westview. Namely, in 2001 the Federal Circuit determined that indefiniteness should be treated the same way that the Supreme Court had decreed claim construction should be treated—as a pure issue for the Court, without any right to a jury trial. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001).

Prior to *Markman*, lower courts had typically treated indefiniteness under 35 U.S.C. § 112 as involving underlying factual issues for the jury. *See, e.g., Beachcombers v. Wildewood Creative Prods.*, 31 F.3d 1154, 1158 (Fed. Cir. 1994) (reviewing denial of judgment as a matter of law after jury verdict of no indefiniteness; standard of review was whether substantial evidence supported the jury's fact findings on indefiniteness); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (reversing grant of JNOV after jury verdict of no indefiniteness; jury was entitled to rely on expert testimony of definiteness).

Indeed, even in the single pre-*Markman* case relied on by Respondents, indefiniteness was treated as a question of law with underlying factual issues, and it was not simply resolved by the Court on summary judgment. *See N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993) (reversing finding of indefiniteness after bench trial that included expert testimony).

In 1996, however, the Supreme Court considered its seminal *Markman* decision on construction of patent claims. In that case, the Court held that claim construction is a pure procedural exercise for the Court. *See Markman v. Westview Instruments*, 517 U.S. 370, 388 (U.S. 1996). The Supreme Court held that a party does not have a right

to a jury determination on claim construction disputes. *See id.* Subsequently, it is recognized that regardless of any factual disputes, a party never has a right to a jury trial on claim construction disputes. *See Moba v. Diamond Automation*, 325 F.3d 1306, 1313 (Fed. Cir. 2003) ("Claim construction is a question of law and is not the province of the jury.").

In the 2001 *Exxon* decision, the Federal Circuit rolled-up indefiniteness into the claim construction inquiry. The Federal Circuit held that "a determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Exxon*, 265 F.3d at 1376. Indeed, the current test for whether claims are indefinite is whether the claims "are not amenable to construction or are insolubly ambiguous." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1351 (Fed. Cir. 2009). Notably, Petitioner has not found any Federal Circuit cases pre-*Markman* that had applied a claim-construction-like test as in *Exxon* to indefiniteness.[3] In short, contrary to Respondents' arguments, the Federal Circuit fundamentally altered its test for indefiniteness after *Markman*.

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3. Respondents allege that the test for indefiniteness has never changed, that it is "whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification." (Resp. Opp. at 3.) While it is true that this has always been the overall test, however, the Federal Circuit has only articulated its "amenable to claim construction" test as a more specific test for determining indefiniteness post-*Markman*. Moreover, in cases such as this, the central indefiniteness question—whether a claimed property can be measured or calculated—has only been improperly treated as a pure legal issue post-*Markman*.

B. Under The Federal Circuit's Current Law, Indefiniteness Is Never Subject To Underlying Issues of Fact

Respondents are also fundamentally incorrect in arguing that the Federal Circuit currently recognizes that indefiniteness can sometimes be a question of law with underlying factual issues. (*See* Resp. Opp. at 4-8.)

In *Exxon*, the Federal Circuit expressly (but incorrectly) stated that indefiniteness is always a pure question of law with no underlying issues of fact—*Exxon* was not merely a narrow, fact-specific holding as Respondents allege:

> Despite a multitude of recent authorities stating that indefiniteness is a question of law, Exxon contends that indefiniteness depends on underlying questions of fact. It argues that in this case there is a genuine issue of material fact as to whether the claims of the two patents at issue, read in light of their specifications, reasonably apprise those skilled in the art of the scope of the invention. . . . We adhere to the principle that "determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." . . . We therefore reject Exxon's argument that the issue of indefiniteness turns on an underlying factual dispute that should not have been resolved as a matter of law on summary judgment.

Exxon, 265 F.3d at 1376 (emphasis added).

Subsequent Federal Circuit and district court decisions confirm that *Exxon*'s holding broadly applies to any indefiniteness inquiry. *See, e.g., Baker Hughes, Inc. v. Davis-Lynch, Inc.*, 31 Fed. Appx. 650, 654 (Fed. Cir. 2002) (nonprecedential) ("Whether a claim has indeed failed to disclose sufficient structure, and is thus indefinite, is a question of law which we review de novo. We have specifically rejected the contention that this process involves underlying issues of fact."); *Wellman, Inc. v. Eastman Chem. Co.*, 689 F. Supp. 2d 705, 720 (D. Del. 2010) ("The Federal Circuit has held that it is appropriate to render a patent invalid for indefiniteness even in the presence of an underlying factual dispute."); *Romala Stone, Inc. v. Home Depot U.S.A., Inc.*, 2007 U.S. Dist. LEXIS 73098, 17-18 (N.D. Ga. Sept. 28, 2007) ("The Federal Circuit Court of Appeals has rejected the argument that claim construction turns on underlying factual disputes and has reaffirmed its holding that claim construction is a purely legal determination.") (internal citations omitted).

Respondents' attempts to argue otherwise are inapposite, and are based entirely on (1) dicta; (2) a holding on an unrelated issue (i.e., whether it is permissible (rather than required) to give the indefiniteness issue to the jury); (3) a pre-*Exxon* district court decision; and (4) a single outlier district court decision that failed to consider *Exxon*.

For example, in *Green Edge*, the Federal Circuit relied entirely on the law that "a showing of indefiniteness requires clear and convincing evidence" in affirming the district court's denial of summary judgment of indefiniteness. *See Green Edge Enters., LLC v. Rubber*

Mulch Etc., LLC, 620 F.3d 1287, 1299 (Fed. Cir. 2010). The Federal Circuit's statement that indefiniteness is a "question of law with underlying factual determinations" was merely dicta, and failed to consider *Exxon* or its progeny. *See id.*

Likewise, in *BJ Services*, the Federal Circuit was merely considering whether it was permissible to give the issue of indefiniteness to the jury as a matter of the Court's discretion. *See BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003). The Federal Circuit did not consider whether underlying factual disputes required the Court to give the question of indefiniteness to the jury, or whether such underlying factual disputes would preclude summary judgment. Indeed, the Court in *BJ Services* could have simply overturned the jury verdict. Accordingly, lower courts have reconciled *BJ Services* and *Exxon* by explaining that (1) *BJ Services* permits a court to give indefiniteness to a jury, but (2) *Exxon* mandates that a party is not entitled to a jury trial on indefiniteness, regardless of underlying factual issues. *See, e.g., Fujitsu Ltd. v. Tellabs Operations, Inc.*, 2011 U.S. Dist. LEXIS 35286 (N.D. Ill. Mar. 31, 2011) ("In *BJ Services*, the Federal Circuit . . . did not discuss whether such factual issues preclude summary judgment on the definiteness issue."). In other words, *Exxon* held that factual disputes can never preclude summary judgment on indefiniteness and result in a jury trial, and *BJ Services* never held to the contrary.[4]

4. Petitioner does not agree that *BJ Services* holds, contrary to *Exxon*, that indefiniteness entails underlying issues of fact for a jury. Even if true, however, that would mean that the Federal Circuit's law is inconsistent, requiring the Supreme Court to resolve the issue.

Further, Respondents rely on two district court cases that purportedly have treated indefiniteness as a question of law with underlying factual issues. (*See* Pet. Opp. at 4-5.) Respondents, however, ignore that the first case, *Systems Management Arts*, was decided before the Federal Circuit's September 2001 *Exxon* decision. *See System Mgmt. Arts, Inc. v. Avesta Techs., Inc.*, 137 F. Supp. 2d 382 (S.D.N.Y. 2001). Meanwhile, the *Dow Chemical Co.* decision, relying primarily on the *System Management* decision and never citing the Federal Circuit's *Exxon* decision, is an outlier decision, which directly contradicts the Federal Circuit's current law. *See Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 629 F. Supp. 2d 397, 404 (D. Del. 2009).

III. THE DISTRICT COURT IMPROPERLY RESOLVED INDEFINITENESS AS A PURE ISSUE OF LAW AND RULED ON FACTUAL ISSUES

Even if Respondents were correct that Federal Circuit law does recognize underlying issues of fact on indefiniteness, there is no question that the District Court did not do so. In its decision granting summary judgment of indefiniteness, the District Court relied heavily on the Federal Circuit's *Exxon* decision and stated that:

> Whether a particular patent is invalid for indefiniteness presents a question of law, because claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims. Indefiniteness remains a matter of law, and the proper province of the court, even when

> the determination of claim's indefiniteness depends on an underlying issue of fact. In such circumstances the court will consider those underlying factual issues and rule on indefiniteness as a matter of law on summary judgment.

(Petition App. at 35a-36a.) (emphasis added).

Contrary to Respondents' characterizations, the District Court did not determine that no underlying factual disputes existed because Petitioner's evidence was allegedly conclusory or contradicted by the patents or prior testimony. Rather, the District Court weighed that testimony as a factual matter and nevertheless granted summary judgment. (*See* Petition App. at 12c (considering Petitioner's expert testimony as "less significant" than Respondents' arguments regarding the intrinsic evidence).) The Federal Circuit subsequently affirmed, and did not find that the District Court should have given those underlying factual issues to the jury. By doing so, the District Court and the Federal Circuit improperly denied Petitioner its Seventh Amendment right to a trial by jury, and continued to incorrectly treat indefiniteness as a pure issue of law.

CONCLUSION

To give proper direction to the Federal Circuit and to the public on important patent rights and the proper framework for determining patent invalidity for indefiniteness, the petition for a writ of certiorari should be granted.

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